DRUG UTILIZATION EVALUATION OF ANTIBIOTICS AT A TERTIARY CARE HOSPITAL

A Dissertation submitted to
THE TAMIL NADU Dr. M.G.R. MEDICAL UNIVERSITY,
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In partial fulfillment of the requirements for the award of the Degree of
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Submitted by
Mr. SANOJ PANICKER
REGISTRATION No.261440117

Under the guidance of
Mrs. CHITRA.B, M.Pharm., (Ph.D).,
Department of Pharmacy Practice

COLLEGE OF PHARMACY
SRI RAMAKRISHNA INSTITUTE OF PARAMEDICAL SCIENCES
COIMBATORE - 641 044.

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CERTIFICATE

This is to certify that the M.Pharm Dissertation entitled "**Drug Utilization Evaluation of Antibiotics at a Tertiary Care Hospital"** being submitted to The Tamil Nadu Dr. M.G.R Medical University, Chennai was carried out by **Mr.Sanoj Panicker** in the Department of Pharmacy Practice, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore, under my direct supervision and guidance to my fullest satisfaction.

Mrs. Chitra.B, M.Pharm., (Ph.D).,
Assistant Professor,
Department of Pharmacy Practice,
College of Pharmacy,
SRIPMS,
Coimbatore- 641 044

Place : Coimbatore
Date :

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Dr. S. Sriram, M.Pharm.,Ph.D.,
Professor and Head,
Department of Pharmacy Practice,
College of Pharmacy,
SRIPMS,
Coimbatore- 641 044

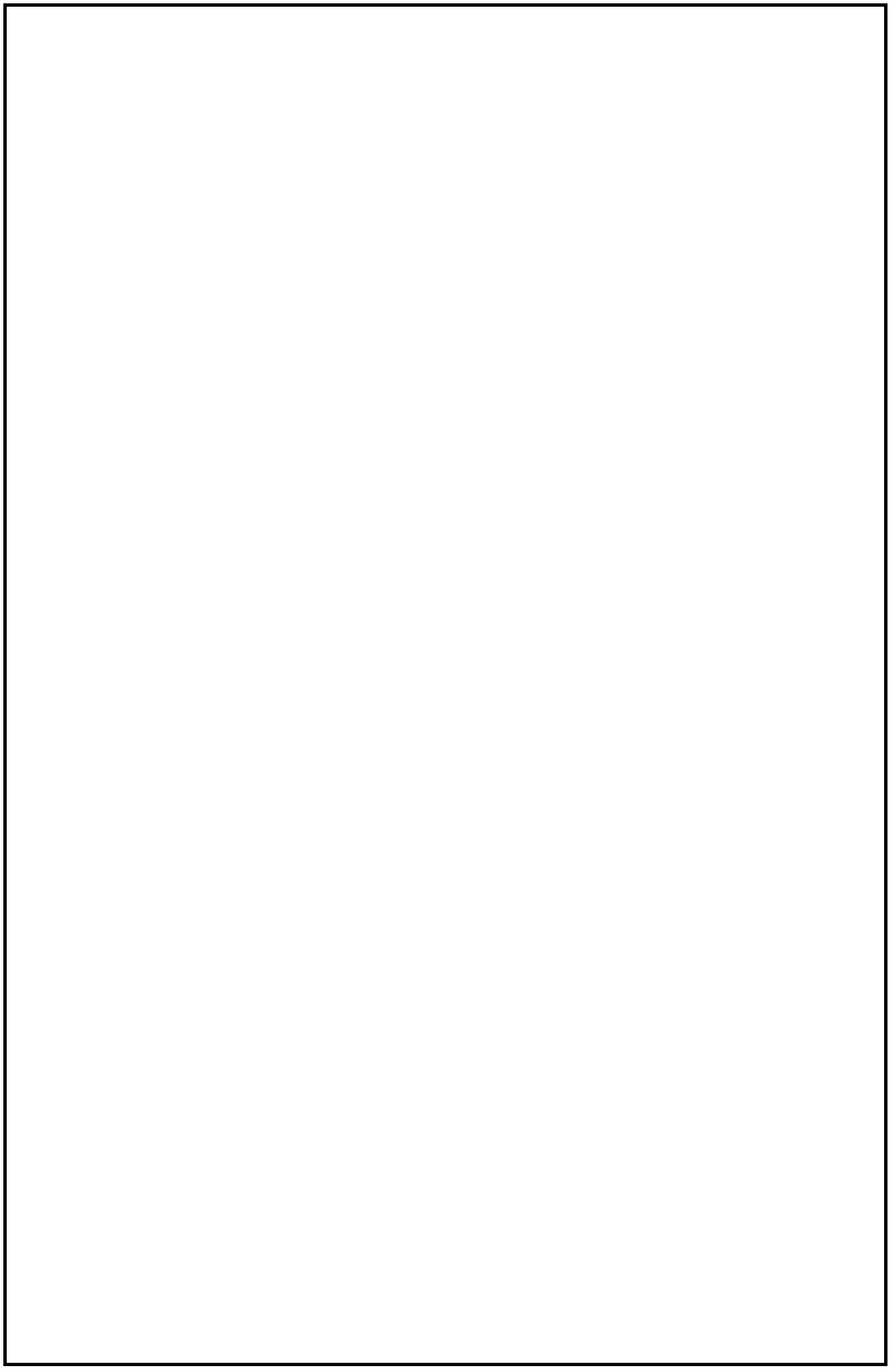
Place : Coimbatore
Date :

CERTIFICATE

Drug Utilization Evaluation of Antibiotics at a Tertiary Care Hospital" being submitted to **The Tamil Nadu Dr. M.G.R Medical University, Chennai** was carried out by **Mr.Sanoj Panicker** in the Department of Pharmacy Practice**,** College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore, under the direct supervision and guidance of **Mrs.Chitra. B, M.Pharm., (Ph.D).,** Assistant Professor and Head Department of Pharmacy Practice, College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore.

Dr. T. K. Ravi, M. Pharm., Ph.D.,FAGE.,
Principal
College of Pharmacy,
SRIPMS,
Coimbatore- 641 044

Place : Coimbatore
Date :



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ABSTRACT

Drug utilization evaluation studies plays an important role in identifying the prescription pattern among the patients which helps in providing a useful information for improvement of the appropriate and effective use of antibiotics and also developing the proper protocols for the use of antibiotic in hospitals. This was a prospective observational study carried out in general medicine department over a period of 10 months enrolling 150 patients. The study was carried out to assess prescribing pattern, sensitivity pattern, adverse reaction involved and cost comparison of antibiotics prescribed in 150 patients. Also DDD/ 100bed- days and ATC of 10 commonly prescribed antibiotics were calculated. Most commonly prescribed antibiotics were Piperacillin / tazobactum followed by Ceftriaxone. During the study period 12 ADR was reported and most of adverse drug reactions (ADR) was observed in the age group of 61-80 years. The antibiotic sensitivity pattern was analysed which revealed that Klebsiella pneumonia was highly sensitive to Amikacin and Imipenem, E. coli was sensitive to Piperacillin/ tazobactum, E. faecalis was sensitive to Piperacillin/ tazobactum, gentamycin and Ofloxacin and Streptococcus. Aureus was sensitive to Imipenem, Meropenam and Ceftriaxone. The total cost was Rs. 1945.29±2175.39 for the prescribed antibiotics whereas for alternate antibiotics the cost was Rs. 1169.63±1282.04, which would help in minimising the patient's expenditure. Clinical pharmacists and Clinicians need to play vital role in minimizing the antibiotic problems by conducting continual awareness programs regarding up-to-date prescribing guidelines in the hospital and also minimizing the antibiotic resistance. Therefore drug utilization review programme must be carried out to study the rational use of antimicrobials.

ABBREVIATIONS

ADR	Adverse Drug Reaction
ATC	Anatomical Therapeutic Classification
AOSD	Adult onset Still's Disease
APTT	Active Partial Thromboplastin Time
ADRAC	Adverse drug reaction advisory committee
BPI	Bacteriologically Proven Infection
BA	Bronchial Asthma
COPD	Chronic Obstructive Pulmonary disease
CRF	Chronic Renal Failure
CVA	Cerebrovascular Accident
DUE	Drug Utilisation Evaluation
DDD	Daily Defined Dose
DI	Drug Interaction
DCM	Dilated Cardiomyopathy
DM	Diabetes Mellitus
EAG	Estimated Average Glucose
eGFR	Estimated Glomerular Filtration Rate
GGT	Gama GlutamylTransferase
GIT	Gastrointestinal Tract
GW	General Ward
HD	Haemodialysis
ICU	Intensive Care Unit
INRUD	International network for the Rational Use of Drugs
IHD	Ischemic Heart Disease
IPC	Indian Pharmacopoeia Commission
LRTI	Lower Respiratory Tract Infection
ME	Medication Error
NHS	National Health Service
NSAID	Non Steroidal Anti inflammatory Drug

OPD	Out Patient Department
PCT	Procalcitonin
PT	Prothrombin Time
PMS	Post marketing Surveillance
PPMS	Prescription Pattern Monitoring Studies
POM	Prescription Only Medicine
RUM	Rational Use Of Medicines
STEMI	ST Elevated Myocardial Infraction
SHT	Systemic Hypertension
SPSS	Statistical Package for the Social Services
TSH	Thyroid Stimulating Hormone
UV	Ultra violet
UTI	Urinary Tract Infection

INTRODUCTION

Antibiotics are powerful and effective drugs in fighting against infectious diseases caused by bacteria and have been frequently used for decades worldwide for effective treatment of a variety of bacterial infections. Antibiotics have saved millions of lives since their first appearance about fifty years ago. [1]

Antibiotics are drugs used to treat bacterial infections. Antibiotics have no effect on viral infections. Originally, an antibiotic was a substance produced by one microorganism that selectively inhibits the growth of another. Synthetic antibiotics, usually chemically related to natural antibiotics, have since been produced that accomplish comparable tasks.

In 1926, Alexander Fleming discovered penicillin, a substance produced by fungi that appeared able to inhibit bacterial growth. In 1939, Edward Chain and Howard Florey further studied penicillin and later carried out trials of penicillin on humans (with what were deemed fatal bacterial infections). Fleming, Florey and Chain shared the Nobel Prize in 1945 for their work which ushered in the era of antibiotics.

Antimicrobials can be classified based on :[2]

1. Spectrum of activity
2. Effect on bacteria
3. Mode of action

- Classification according to spectrum of activity

Depending on the range of bacterial species susceptible to these agents, antibacterials are classified as broad-spectrum, intermediate-spectrum, and narrow- spectrum.

1. Broad spectrum antibacterials are active against both Gram-positive and Gram-negative organisms. Examples include: tetracyclines, Phenicols,

Fluoroquinolones, "third-generation" and "fourth-generation" Cephalosporins.

2. Narrow spectrum antibacterials have limited activity and are primarily only useful against particular species of microorganisms. For example, Glycopeptides and Bacitracin are only effective against Gram-positive bacteria, whereas Polymixins are usually only effective against Gram negative bacteria. Aminoglycosides and Sulfonamides are only effective against aerobic organisms, while nitroimidazoles are generally only effective for anaerobes.

- Effect on Bacteria

Because of differences in the mechanisms by which antibiotics affect bacteria, the clinical use of antibacterials may have very different effects on bacterial agents, leading to an endpoint of either inactivation or actual death of the bacteria.

1. Bactericidal drugs are those that kill target organisms. Examples of Bactericidal drugs include Aminoglycosides, Cephalosporins, Penicillins, and Quinolones.

2. Bacteriostatic drugs inhibit or delay bacterial growth and replication. Examples of such include tetracyclines, Sulfonamides, and Macrolides.

Some antibiotics can be both bacteriostatic and bactericidal, depending on the dose, duration of exposure and the state of the invading bacteria. For example, Aminoglycosides, Fluoroquinolones, and Metronidazole exert concentration-dependent killing characteristics; their rate of killing increases as the drug concentration increases.

- Mode of Action

Different antibiotics have different modes of action, owing to the nature of their structure and degree of affinity to certain target sites within bacterial cells.

1. Inhibitors of cell wall synthesis. While the cells of humans and animals do not have cell walls, this structure is critical for the life and survival of bacterial species. A drug that targets cell walls can therefore selectively kill or inhibit bacterial organisms. Examples: Penicllins, Cephalosporins, Bacitracin and Vancomycin.

2. Inhibitors of cell membrane function. Cell membranes are important barriers that segregate and regulate the intra- and extracellular flow of substances. A disruption or damage to this structure could result in leakage of important solutes essential for the cell's survival. Because this structure is found in both Eukaryotic and Prokaryotic cells, the action of this class of antibiotic are often poorly selective and can often be toxic for systemic use in the mammalian host. Most clinical usage is therefore limited to topical applications. Examples: Polymixin B and Colistin.

3. Inhibitors of protein synthesis. Enzymes and cellular structures are primarily made of proteins. Protein synthesis is an essential process necessary for the multiplication and survival of all bacterial cells. Several types of antibacterial agents target bacterial protein synthesis by binding to either the 30S or 50S subunits of the intracellular ribosomes. This activity then results in the disruption of the normal cellular metabolism of the bacteria, and consequently leads to the death of the organism or the inhibition of its growth and multiplication. Examples: Aminoglycosides, Macrolides, Lincosamides, Streptogramins, Chloramphenicol, tetracyclines.

4. Inhibitors of nucleic acid synthesis. DNA and RNA are keys to the replication of all living forms, including bacteria. Some antibiotics work

by binding to components involved in the process of DNA or RNA synthesis, which causes interference of the normal cellular processes which will ultimately compromise bacterial multiplication and survival. Examples: Quinolones, Metronidazole, and Rifampin.

5. Inhibitors of other metabolic processes. Other antibiotics act on selected cellular processes essential for the survival of the bacterial pathogens. For example, both Sulfonamides and Trimethoprim disrupt the Folic acid pathway, which is a necessary step for bacteria to produce precursors important for DNA synthesis. Sulfonamides target and bind to dihydropteroate synthase, Trimethophrim inhibit dihydrofolate reductase; both of these enzymes are essential for the production of folic acid, a vitamin synthesized by bacteria, but not humans.

CLASSIFICATION OF ANTIBACTERIAL AGENTS

Antibiotics Classification[14]

Although there are several classification schemes for antibiotics, based on bacterial spectrum (Broad versus Narrow) or type of activity (Bactericidal vs. Bacteriostatic), the most useful is based on chemical structure. Antibiotics within a structural class will generally have similar patterns of effectiveness, toxicity, and allergic potential.

The main classes of antibiotics are:

- Beta-Lactams
- Penicillins
- Cephalosporins
- Macrolides
- Fluoroquinolones
- Tetracyclines
- Aminoglycosides

Most commonly used types of antibiotics are: Aminoglycosides, Penicillins, Fluoroquinolones, Cephalosporins, Macrolides, and Tetracyclines. While each class is composed of multiple drugs, each drug is unique in some way.

Penicillins

The penicillins are the oldest class of antibiotics. Penicillins have a common chemical structure which they share with the Cephalosporins.

Penicillins are generally bactericidal, inhibiting formation of the bacterial cell wall. Penicillins are used to treat Skin infections, Dental infections, Ear infections, Respiratory tract infections, Urinary tract infections, Gonorrhea.

There are four types of penicillins:

- **The natural penicillins** are based on the original penicillin-G structure. Penicillin-G types are effective against gram-positive strains of Streptococci, Staphylococci, and some gram-negative bacteria such as meningococcus.
- **Penicillinase-resistant penicillins**, notably methicillin and oxacillin, are active even in the presence of the bacterial enzyme that inactivates most natural penicillins.
- **Aminopenicillins** such as Ampicillin and Amoxicillin have an extended spectrum of action compared with the natural penicillins. Extended spectrum penicillins are effective against a wider range of bacteria.
- ***Extended-spectrum penicillins*** are piperacillin and ticarcillin.

Penicillins side effects

Penicillins are among the safest and least toxic drugs. The most common side effect of penicillin is Diarrhoea. Nausea, Vomiting, and stomach upset are also common. In rare cases penicillins can cause immediate or delayed allergic reactions which manifest as Skin rashes, Fever, Angioedema, and Anaphylactic shock. Severe hypersensitivity reactions are more common after injections than after oral formulations.

Neurotoxicity

Very high doses of penicillins, especially in patients with renal impairment, may cause convulsions[5].

In pregnancy category penicillins come under class B category.

Cephalosporins

Cephalosporins have a mechanism of action identical to that of the penicillins. However, the basic chemical structure of the penicillins and cephalosporins differs in other respects, resulting in different spectrum of antibacterial activity. Like the penicillins, cephalosporins have a beta-lactam ring structure that interferes with synthesis of the bacterial cell wall and so is bactericidal. Cephalosporins are derived from cephalosporin C which is produced from *Cephalosporium acremonium*.

Cephalosporins are used to treat pneumonia, tonsillitis, bronchitis, otitis media, various types of skin infections, gonorrhoea, urinary tract infections Cephalosporin antibiotics are also commonly used for surgical prophylaxis. Cephalexin can also be used to treat bone infections.

Cephalosporins are among the most diverse classes of antibiotics, they are grouped into "generations" by their antimicrobial properties. Each newer generation has a broader spectrum of activity than the one before.

- ***The first generation*** cephalosporins have quite similar spectrums of activity. They have excellent coverage against most gram-positive pathogens but contribute to poor coverage against most gram negative pathogens. The first generation includes:

- cephalothin
- cefazolin
- cephapirin
- cephradine
- cephalexin
- cefadroxil

- ***The second generation*** cephalosporins have expanded gram negative spectrum in addition to the gram positive spectrum of the first generation cephalosporins. Cefoxitin and cefotetan have good activity against *Bacteroides fragilis*. Enough variation exists between the second generation cephalosporins in regard to their spectrums of activity against most species of gram negative bacteria, that susceptibility testing is generally required to determine sensitivity. The second generation includes:

- cefaclor
- cefamandole
- cefonicid
- ceforanide
- cefuroxime

- ***The third generation*** cephalosporins have much expanded gram negative activity. However, some members of this group have decreased activity against gram-positive organisms. They have the advantage of convenient administration, but they are expensive. The third generation includes:

- cefcapene
- cefdaloxime
- cefditoren
- cefetamet
- cefixime
- cefmenoxime
- cefodizime
- cefoperazone
- cefotaxime
- cefpimizole
- cefpodoxime
- ceftibuten
- ceftriaxone

- ***The fourth generation*** cephalosporins are extended-spectrum agents with similar activity against gram-positive organisms as first-generation cephalosporins. They also have a greater resistance to beta-lactamases than the third generation cephalosporins. Many fourth generation cephalosporins can cross blood brain barrier and are effective in meningitis. The fourth generation includes:

- cefclidine
- cefepime
- cefluprenam
- cefozopran
- cefpirome
- cefquinome

Cephalosporins side effects

Cephalosporins are remarkably safe class of antibiotics and usually cause few adverse effects. Common side effects include: diarrhoea, nausea, mild stomach cramps or upset. Approximately 5–10% of patients with allergic hypersensitivity to penicillins will also have cross-reactivity with cephalosporins. Thus, cephalosporin antibiotics are contraindicated in people with a history of allergic reactions (urticaria, anaphylaxis, interstitial nephritis, etc) to penicillins or cephalosporins.

Hematologic toxicity

Thrombocytopenia, neutropenia, abnormalities of platelet function and coagulation have been reported with certain cephalosporins [6]

Cephalosporin antibiotics are classed under Pregnancy category B.

Fluoroquinolones (Synthetic Antibiotic)

Fluoroquinolones (fluoridated quinolones) are the newest class of antibiotics. Their generic name often contains the root "floxacin". They are synthetic antibiotics, and are not derived from bacteria. Fluoroquinolones belong to the family of antibiotics called Quinolones. The older quinolones are not well absorbed and are used to treat mostly urinary tract infections. The newer fluoroquinolones are broad-spectrum bacteriocidal drugs that are chemically unrelated to the penicillins or the cephalosporins. Because of their excellent absorption fluoroquinolones can be administered not only intravenously but orally as well.

Fluoroquinolones are used to treat urinary tract infections, skin infections, and respiratory infections (such as sinusitis, pneumonia, bronchitis).

Fluoroquinolones are bacteriocidal and kill bacteria by interfering with their ability to make DNA. This activity makes it difficult for bacteria to multiply.

Fluoroquinolones comprises of :

- ciprofloxacin
- levofloxacin
- lomefloxacin
- norfloxacin
- sparfloxacin
- clinafloxacin
- gatifloxacin
- ofloxacin
- trovafloxacin

Fluoroquinolones side effects

Fluoroquinolones are well tolerated and relatively safe. The most common side effects include nausea, vomiting, diarrhoea, abdominal pain. More serious but less common side effects are central nervous system abnormalities (headache,

confusion and dizziness), phototoxicity (more common with lomefloxacin and sparfloxacin), QT interval prolongation[7], Tendinopathy and tendon rupture[8], and Convulsions[9].

Fluoroquinolones are generally not recommended for pregnant women and children.

Tetracyclines

Tetracyclines got their name because they share a chemical structure that has four rings. They are derived from a species of *Streptomyces* bacteria.

Tetracycline antibiotics are broad-spectrum bacteriostatic agents and work by inhibiting the bacterial protein synthesis. Tetracyclines may be effective against a wide variety of micro-organisms, including rickettsia and amoebic parasites.

Tetracyclines are used in the treatment of infections of the respiratory tract, sinuses, middle ear, urinary tract, skin, intestines. Tetracyclines also are used to treat Gonorrhoea, Rocky Mountain spotted fever, Lyme's disease, typhus. Their most common current use is in the treatment of moderately severe acne and rosacea.

Tetracycline antibiotics are:

- Tetracycline
- Doxycycline
- Minocycline
- Oxytetracycline

Tetracyclines side effects

Common side effects associated with tetracyclines include cramps or burning of the stomach, diarrhea, nausea, vomiting, esophageal ulceration, sore mouth or tongue. Tetracyclines can cause skin photosensitivity, which increases the risk of sunburn under exposure to UV light. Rarely, tetracyclines may cause

allergic reactions. Very rarely severe headache and vision problems may be signs of dangerous secondary intracranial hypertension.

Tetracycline antibiotics should not be used in children under the age of 8, and specifically during periods of tooth development. Tetracyclines are classed under pregnancy category D. Tetracyclines may cause the gray to yellow discoloration of actively forming teeth and deposition in growing bones.

Macrolides

The macrolide antibiotics are derived from Streptomyces bacteria, and got their name because they all have a macrocyclic lactone chemical structure.

The macrolides are bacteriostatic, binding with bacterial ribosomes to inhibit protein synthesis. Erythromycin, the prototype of this class, has a spectrum and use similar to penicillin. Newer members of the group, Azithromycin and Clarithyromycin, are particularly useful for their high level of lung penetration. Macrolide antibiotics are used to treat respiratory tract infections (such as pharyngitis, sinusitis, and bronchitis), genital, gastrointestinal tract, and skin infections.

Macrolide antibiotics are:

- Erythromycin
- Clarithromycin
- Azithromycin
- Dirithromycin
- Roxithromycin
- Troleandomycin

Macrolides side effects

Side effects associated with macrolides include nausea, vomiting, and diarrhoea; infrequently, there may be temporary auditory impairment. Azithromycin has been rarely associated with allergic reactions, including angioedema, anaphylaxis, and dermatologic reactions. Oral erythromycin may be

highly irritating to the stomach and when given by injection may cause severe phlebitis. Macrolide antibiotics should be used with caution in patients with liver dysfunction.

Pregnancy category B: Azithromycin, erythromycin.

Pregnancy category C: Clarithromycin, dirithromycin, troleandomycin.

Aminoglycosides

Aminoglycosides are derived from various species of *Streptomyces*.The aminoglycosides are bactericidal and work by stopping bacteria from making proteins.

Aminoglycoside antibiotics are used to treat infections caused by gram-negative bacteria. Aminoglycosides may be used along with penicillins or cephalosporins to give a two-prolonged attack on the bacteria. Aminoglycosides work quite well, but bacteria can become resistant to them. Since aminoglycosides are broken down easily in the stomach, they can't be given by mouth and must be injected. Generally, Aminoglycosides are given for short time periods.

Aminoglycoside group includes:

- amikacin
- gentamicin
- kanamycin
- neomycin
- streptomycin
- tobramycin

Aminoglycosides side effects

The major irreversible toxicity of aminoglycosides is ototoxicity[10] (damage to the ear and hearing). Among them, streptomycin and gentamicin are primarily vestibulotoxic, whereas amikacin, neomycin, dihydrosterptomycin, and kanamicin are primarily cochleotoxic.

Another significant concern with aminoglycoside antibiotics is nephrotoxicity[11] (kidney damage). Renal damage is related to the accumulation of high concentrations of aminoglycoside antibiotic in the renal cortex.

Aminoglycosides are classed under Pregnancy Category D

Drug Utilization Evaluation

Drug Utilization Evaluation (DUE), is defined as an authorized, structured, ongoing review of healthcare provider prescribing, pharmacist dispensing, and patient use of medication. Drug utilization evaluations involve a comprehensive review of patient's prescription and medication data before, during, and after dispensing to ensure appropriate medication decision making and positive patient outcomes.[5]

Drug therapy is considered to be major component of patient management in healthcare settings, including primary healthcare. Although the benefit patients gains from pharmacological interventions are valuable, the risks of drugs and consequences of inappropriate use cannot be overlooked.[3] The introduction of potent drugs with an increased incidence of adverse drug reactions, the high cost of medication, and a focus on drug use outcomes and the clinical misuse of drugs may result in preventable patient morbidity and mortality, costly remedial care, additional cost for diagnosis and management of iatrogenic disease and unnecessary wastage of health resources. Inadequate knowledge of treatment regimens, lack of diagnostic competence have contributed to incorrect drug choices, incorrect dose, adverse drug reactions, drug interactions, and use of more expensive drugs when less expensive drugs would be equally or more effective. In recognition to this problem, DUE (Drug Utilization Evaluation) has been recommended as a method for identifying inappropriate or unnecessary drug use that monitor, evaluate and promote rational drug therapy. Several factors like irrational drug use, polypharmacy, incorrect drug choices, incorrect dose, drug interactions, have contributed to increased morbidity, mortality and health care

expenses or use of drugs devoid of proven efficacy.[3] The misuse or inappropriate use of antibiotics leads to increase in healthcare expenses, development of drug resistance and serious adverse drug reactions.

Drug utilization evaluation studies plays important role in identifying the prescription pattern among the patients which helps in provide useful information for improvement of the appropriate and effective use of antibiotics and also developing the proper protocols for the use of antibiotic in hospitals.

Prescription pattern monitoring studies (PPMS) are a tool for assessing the prescribing, dispensing and distribution of medicines. Prescription pattern monitoring studies (PPMS) are drug utilization studies with the main focus on prescribing, dispensing and administering of drugs. They promote appropriate use of monitored drugs and reduction of abuse or misuse of monitored drugs. Drug Utilization Evaluation (DUE) studies are designed to assess drug usage appropriateness. Drug utilization studies have the potential to make objective evaluation and analysis of health professionals work and provide them with feedback to stimulate thinking about their practice and looking for ways to improve their own performance. To improve the overall drug use, especially in developing countries, international agencies like the (WHO) World health organization and International network for the rational use of drugs (INRUD) have applied themselves to evolve standard drug use indicators. An audit of antibiotic prescribing patterns is an important indicator of the quality and standard of clinical practice. A systematic review of prescription pattern monitoring studies and their effectiveness in promoting rational use of medicines need to be carried out. The main aim of PPMS is to facilitate rational use of medicines (RUM); and avoid over prescription of antibiotics or misuse of antibiotics, as it may lead to antibiotic drug resistances.[12]

Drug utilization studies are powerful tools to ascertain the role of drugs in the society. They provide a sound socio-medical and health economic basis for

health care decision making. To achieve this, it is very important to determine the drug use pattern and to monitor the drug use profiles, over time, by using the Anatomic Therapeutic Chemical Classification (ATC) /defined daily dosage (DDD) system to serve as a tool for drug utilization in order to improve the quality of drug use. The WHO specifies drug use indicators for adoptions in the drug utilization studies.[5]

Drug utilization evaluation aims to assess whether drug therapy is rational or not. To reach this goal, methods for auditing drug therapy towards rationality are necessary. Drug utilization evaluation can be divided into descriptive and analytical studies. The emphasis of the former has been to describe patterns of drug utilization and to identify problems deserving more detailed studies. Analytical studies try to link data on drug utilization to figures on morbidity, outcome of treatment, and quality of care, with the ultimate goal to assess whether drug therapy is rational or not.

A plethora of drug utilization studies focused on assessing patterns of drug prescribing as a mean of pin- pointing areas for improvement with the aim to rationalize drug use. The health threats that can be caused by improper prescribing cannot be overlooked. Improper prescribing can cause toxicity for patients and will be a waste of money and time. It can also cause therapeutic failure that results in progress of disease conditions and worsening of the patient health condition. The improper prescribing and excessive use of antibiotics can lead to loss of the effectiveness of currently used antibiotics. The World Health Organization (WHO) has repeatedly emphasized the importance of drug utilization studies and developed indicators examine trends of prescribing and the health facilities. Once irrational drug use in its various forms is determined, feasible means of intervention are tried with the hope to improve drug use. [6]

Antibiotic resistance was recognized by the World Health Organization as a serious phenomenon which has emerged due to the pervasive prescription of antibiotics in practice.

The development of bacterial resistance to antibiotics has become a major problem throughout the world. Resistant organisms may emerge as a result of many factors, including widespread usage, while their spread is mainly caused by factors in the health care setting, including the health care providers' behaviour. The broadest-spectrum antibiotics, such as fourth-generation cephalosporins, piperacillin-tazobactam and Carbapenems, play an important role in the empiric therapy of serious nosocomial infections. These antimicrobials are also among the most expensive.[4] Concern about escalating rates of multi-drug-resistant organisms and spiralling expenditure on broad-spectrum antimicrobials has induced most hospitals to implement a range of measures. These include supervision of their use by infectious disease consultants and/or clinical pharmacists, provision of continuing education regarding appropriate antimicrobial drug use, and implementation of automatic stop orders. However, there is evidence that, in order to be effective, a multidisciplinary approach is warranted, with application of a range of measures, some of which should be individualized according to the hospital's circumstances and means. Thus one of the methods increasingly used in this era of cost constraints and quality assurance is drug utilization evaluation (DUE). This tool was adapted by pharmacists to assess appropriateness of usage of various medications.[4]The purpose of a DUE is generally to detect possible problems with, and improve, drug use. DUEs have traditionally focused on drugs with frequent side-effects, high price tags or complicated dosing regimens. Very few DUEs have addressed broadest-spectrum antibiotics, and none has included all three last-line agents.

Excessive prescription of antibiotics not only increases the burden of antibiotic resistance but also exposes patients to the side effects of these drugs and increases the treatment costs. Research and evaluation of antibiotic utilization and antibiotics cost plays an important role in identifying the extent, quality, necessity, and outcome of antibiotic use. Moreover, calculating the cost of antibiotics prescribed. [7]

According to WHO the rational use of drugs is the use of the right drug, right dosage at the right cost. "Rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, at the lowest cost to them and their community."

Antibiotic drug resistance can be intrinsic or acquired, develops due to irrational use of antibiotics. Developing new antibiotics is not a solution for this. It is the responsibility of the healthcare team to develop a good prescribing pattern which will help in reducing the intensity of the problem. And most of the alternatives, i.e. second and third line agents are becoming ineffective in clinical practice. [8]

Microbial resistance to antibiotics is a matter of great importance if sensitive strains are supplanted by resistant ones, then a valuable drug may become useless. Based on the mechanism, resistance can be classified as: Naturally acquired resistance, acquired drug resistance, tolerance (adaptation), “single step” chromosomal mutation and transmissible drug resistance.[13]

Surveillance of bacterial resistance is a key element in understanding the size of the problem. The large number of existing networks of resistance surveillance needs to be coordinated, and the results made available. To help doctors choose appropriate antibiotics and to detect local epidemics of resistant bacteria surveillance at local level is necessary by resistance can be minimized. There are two-ways of fighting the development and spread of resistance. The first is to reduce the use of antimicrobial agents. About 85-90% of antibacterial drugs are used in the community, and up to 80% of these are used to treat respiratory tract infections. Sales of antibiotics over the counter should be stopped. The second major way to tackle resistance is by improving hygiene measures to prevent the spread of transmissible diseases. In hospitals, effective prevention of cross infection and the development of strict antibiotic policies should be in the hands of experts. Each hospital thus needs an infection control team with

infectious disease specialties, clinical microbiologists, and infection control nurses, and sufficient resources are a mandate to run the program. Antibiotics are prescribed unnecessarily and empirically for complaints where no antibiotic is required or where culture and sensitivity results could be safely awaited. Thus, continuous monitoring of the pattern of bacterial resistance serves as empiric guide for therapy. Empirical antibiotic therapy should be given when bacterial infection is suspected and poses a sufficient health risk to demand immediate treatment. Eg: Pyrexia of unknown origin, Meningitis, Tuberculosis. Problems with empirical therapy are: Prescribing antibiotics to patients who do not have a bacterial infection, inappropriate antimicrobials may be selected. Hence, an urgent need exists for less frequent use and more appropriate selection of antimicrobial drugs. Before starting an antibiotic for a patient, the clinician must consider whether the antibiotic is suitable. The importance of determining the type and sensitivity of the causative organism is obvious. The key action by the clinician should be the provision of a specimen for accurate identification of the offending pathogen by means of culture and sensitivity method .[13]

The study of prescribing patterns seeks to monitor, evaluate and suggest modifications in practitioners' prescribing habits so as to make medical care rational and cost effective. Information about antibiotic use patterns is necessary for a constructive approach to problems that arise from the multiple antibiotics available. [9]

WHO defines an adverse event as any untoward medical effect that occurs during drug therapy but not necessarily with a causal relationship with the treatment. Therefore, from the occurrence's perspective, Adverse Drug Reactions (ADR's) and Medication Error (ME) can be considered adverse drug events. Adverse drug reactions (ADRs) defined by the World Health Organization (WHO) as "any noxious, unintended effect to the use of a drug, which occurs at doses usually used in humans for prophylaxis, diagnosis or therapy or for modifying a physiological action". This definition assumes the correct use of a drug and reflects the intrinsic risk to its use. Therefore, these are non- preventable

events. In contrast, medication errors (MEs) are defined as "any preventable event that may cause patient harm or lead to inappropriate medication use while the medication is in the control of the health care professional, patient, or consumer.[10] Such events may be related to professional practice, procedures, and systems, including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use. Adverse drug events in hospitalized patients are an emerging condition associated to significantly increased hospital stay, costs, and morbidity. Adverse drug events are a public health concern because of its high occurrence incurring in additional costs to health services.[[11]]

The cost of drug therapy is increasing dramatically, especially as new products, derived from various methods, are being introduced. Cost is one among the various factors to be taken into account in antibiotic prescribing. The unnecessary use of antibiotics has imposed a huge burden on the patients. With this basis the study was planned to assess the drug utilization evaluation of antibiotics in the hospital.

Evaluation of prescribing pattern will also help in minimizing adverse drug reactions and it shall also aid in providing cost effective medical care. Therefore, this study would help us to monitor the prescribing pattern and cost of antibiotics so that these can be used judiciously.

LITERATURE REVIEW

1. ***R Selvaraj et al (2015)***[1] conducted a study to assess rational use of antimicrobials in the medicine outpatient department of a teaching hospital. A total of 650 prescriptions were collected from the medicine OPD. Prescriptions containing antimicrobial were grouped using the anatomical therapeutic chemical (ATC) codes. They concluded that higher frequency of irrational antimicrobial prescriptions suggests that antimicrobial restriction policies and a multidisciplinary effort to reduce usage are urgently required.
2. ***Mohanraj Rathinavelu et al (2015)***[2]conducted a study to evaluate the pattern of drug utilization in inpatients of general medicine department. The data for study was obtained from 80 inpatients prescriptions and the DDD/100 bed days were calculated. The study indicate that there improvement in prescribing pattern of antibiotics is possible by adhering to standard guidelines of treatment and restriction policies to promote rational drug use.
3. ***Admane PD et al (2015)***[3]carried out a study to assess the use of antimicrobials in tertiary care hospital. A prospective cross sectional study was conducted in outpatient department over a period of 8 months and total 1942 prescriptions were collected. The study results analysed that the rational use of antimicrobial agents is needed to control antibacterial resistance, side effects and reduced cost of the treatment.
4. ***Greeshma Hanna Varghese et al (2015)***[4]carried out a prospective observational study over a period of months and screened 1139 prescription to assess the patterns of drug utilization evaluation by WHO prescribing indicators among special population in a tertiary care government teaching hospital retrospectively and prospectively. The study concluded that it is necessary to avoid over prescription, follow

guidelines while prescribing drugs generic name, reduce the use of antibiotics after susceptibility testing , to minimize the use of injections and to confine to the National essential drug list are necessary to further improve rational use of drugs.

5. ***Maheshwari P et al (2015)***[5] studied on the patient's awareness on the rational use of antibiotics and its resistance by developing a questionnaire. The study revealed that there was a very high consumption of antibiotics mainly cephalosporin's. Dispensing of antibiotics is very high in community pharmacy despite of federal regulations. They proposed health education programmes should be given to the patients regarding antibiotics.

6. ***Venu Gopal D et al (2014)***[6] conducted a prospective observational study in a tertiary care teaching hospital for six months in general medicine and screened 555 antibiotic prescription. The study concluded that the clinical pharmacists and Clinicians need to play vital role in minimizing the antibiotic problems by conducting continual awareness programs regarding up-to-date prescribing guidelines in the hospital and also minimizing the antibiotic resistance. The active participation of clinical Pharmacists in the clinical ward rounds and documentation of Pharmacist observation on prescription in patient folder is highly recommended for safety and drug monitoring.

7. ***M. Shamna et al (2014)***[7] carried out a prospective study in all departments for a period of one year to detect and analyse adverse drug reaction of antibiotics in inpatients of a tertiary care hospital. The study concluded that adverse drug reaction to antibiotics is getting common and it resulted in increased health care cost and length of hospital stay. Therefore study suggest that health system should promote the spontaneous reporting of adverse drug reaction to antibiotics , proper

documentation and periodic reporting to regional pharmacovigilance centres to ensure drug safety.

8. ***Mujtaba Hussain et al (2014)***[8] conducted a prospective, observational study of antibiotic prescribing patterns at admission in an open, mixed medical surgical, adult, ICU in a tertiary care hospital including 110 patients to determine the group of antibiotics that are prescribed for various illnesses, average number used and the cost of antibiotics per prescription. The study concluded that there is a need for guidelines and protocol for treatment at all levels of health care especially with respect to antibiotics.

9. ***Meher B. R. et al (2014)***[9] conducted a prospective study in 200 patients in general medicine department to obtain information about demographic profiles of patients, prevalence of infectious diseases and prescribing pattern of antibiotics of a tertiary care teaching hospital. The study concluded that a strict protocol for prescribers is required to promote rational use of antibiotics which would not only prevent antibiotic resistance but also reduce the treatment expenditure in hospitals.

10. ***Shalini et al (2011)***[10] studied on antibiotic sensitivity pattern in urinary tract infection at a hospital. The most common samples isolated were Escherichia coli, Klebsiella, Pseudomonas, and Staphylococcus aureus.E.coli showed high sensitivity to Amikacin and Nitrofurantoin. E.coli isolates were also sensitive to Minocycline, showing a good utility of this drug for the treatment for patients with urinary tract infections.

11. ***Mayadah Shehadeh et al (2011)***[11] studied on the knowledge, attitudes and behaviour regarding antibiotics use and misuse among adults in the community of Jordan. The study showed that knowledge of when antibiotics should be used, the efficacy of antibiotics as well as the risk of antibiotic resistance is inadequate in study population. To prevent the inappropriate antibiotics consumption the health authorities had to

implement their regulations to prohibit the selling of Prescription Only Medicine (POM) without prescription.

12. ***Estela Louro et al (2007)***[12]studied on adverse events to antibiotics in inpatients of a university hospital. The aim of the study was to evaluate the occurrence of adverse events to antibiotics in inpatients of a hospital. The study results indicate that an inadequate knowledge on antibiotics or lack of information about the patient at the time of prescription were the major factors involved in the occurrence of adverse event
13. ***M.V. Srishyla,*** **et al (2007)** [13] conducted a study including 556 in patients to assess prescription on the basis of type of use, speciality, site of infection, route of administration and the antimicrobial agent used. The study showed that 56% of in-patients were prescribed antimicrobial agents and 44% of them received a combination of antimicrobials and concluded that there is need of review of antimicrobial prescribing practices.
14. ***David L Peterson (2005)***[14] studied on the role of antimicrobials management programs in optimizing antibiotic prescribing within hospital. The study was mainly done on patients receiving a broad spectrum antimicrobial agent, fluroqunolones, vancomycin and cephalosporin for a period of 48 hours. It was found that the spectrum was too broad on the basis of result of microbiological testing and the use of vancomycin was unnecessary in certain cases.
15. ***Ravi Pathiyil Shankar et al (2003)***[15]carried out a over a period of 3 month including 203 patients study to collect demographic information, antibiotic prescribing patterns, and common organism isolated including antibiotic sensitivity patterns. The study concluded that antibiotic resistance is getting common, therefore formulation of policy for hospital antibiotic use and should organise educational programs especially for junior doctors.

SCOPE OF THE STUDY

Antibiotics are considered as the greatest discovery of the twentieth century. Successful use of antibiotics has brought a revolutionary change in management of infectious diseases but it also resulted over use and misuse of antibiotics. Antibiotics today are commonly prescribed drugs in a hospital set up. The emergence of antibiotic resistant bacteria is a major problem throughout the world and a rational use of antibiotics is therefore very important. Irrational use of antibiotics can cause increase adverse drug reaction, lead to antibiotic resistance and increase the treatment cost. Assessment of pattern of antibiotics utilization is significant in the context of its increase use and its overall impact on the health care system.

Almost one third of the people receive one or the other antibiotics during the course of hospital stay. However antibiotics have become one of the misused therapeutic agents available to the medical profession. One drawback of such large scale use of antibiotic is the emergence of antibiotic resistant pathogens. Antibiotic resistance is the ability of bacteria to repel or withstand the effects of an antibiotic. The increased resistance is a result of many factors, but the foremost cause is the overall volume of antibiotic consumption. Antimicrobial resistance is not only increasing the healthcare costs, but also the severity and death rates from certain infections that could have been avoided by prudent and rational use of the existing and newer antimicrobial agents.

More than 70% of the bacteria that cause hospital acquired infection are resistant to at least one of the drug most commonly used to treat them. Some bacteria are resistant to all approved antibiotics and must be treated with experimental and potentially toxic drugs. Persons infected with drug resistant bacteria are more likely to have longer hospital stays and require treatment with

second or third choice drugs that may be less effective, more toxic and more expensive. Antibiotic resistance is driving up health care cost, increasing the severity of disease and increasing the death rate from certain diseases. The terms methicillin resistant *Staphylococcus aureus*, Vancomycin resistant *enteroccoci* and multidrug resistant tuberculosis are heard all too often in today's world. Prudent and rational use of antibiotics is possible by forming local, national, and global wide antibiogram**.** The antibiotic sensitivity pattern can help in identifying the pathogen responsible for the infection thereby antibiotic susceptible against that particular pathogen can be administered to the patient. The sensitivity pattern has helped in declining the severity and death rate from infection by the prudent and the rational use of antibiotics.

The present study aimed to identify prescribing pattern of antibiotics, ADR involved, antibiotic sensitivity and cost comparison. Drug utilization research facilitates the rational use of drugs and suggests a way to improve prescribing habits.

OBJECTIVES OF THE STUDY

- To study the prescribing pattern of antibiotics.
- To study the pattern of antibiotic sensitivity
- To identify the adverse effects of antibiotics.
- To assess the cost comparison of antibiotics.

PLAN OF THE STUDY

The entire study was planned to be carried out for a period of 10 months from November 2015- August 2016. The proposed study was designed in four phases to achieve the objectives.

PHASE I

- Literature survey
- Preparation of Protocol
- Obtaining consent from the hospital authorities

PHASE II

- Preparation of patient consent form
- Designing of structured data entry format
- Data collection
- Documentation of collected data using the data entry format

PHASE III

- Analysis of all the collected data
- Graphical representation of the data
- Interpretation of the data
- Statistical analysis of all the collected data

PHASE IV

- Preparation of the project report and submission to the study department

METHODOLOGY

STUDY SITE

The proposed work entitled "Drug utilisation and evaluation of antibiotics at a tertiary care hospital" was carried out in a 750 bedded multi-speciality institution, one of largest hospitals in Coimbatore. The various specialities include General Medicine, Anaesthesiology, Orthopaedics, Radiology, Nephrology, Pulmonology and critical care, cardiology, cardiothoracic Surgery, Microbiology, Pathology, Haematology, Laparoscopic surgery, ENT, Dental and Maxillofacial Surgery, Neurology, Ophalmology, Physical Medicine and rehabilitation Diabetology, Surgical Gastro Enterology, Oncology. The hospital is also equipped with the modern diagnostic facilities like CT scan, MRI scan, ultrasound Sonography, Digital Subtraction Angiography (DSA), ECG, Treadmill, Colour Doppler etc. The hospital also has twelve hi-tech operation theatres, Intensive care unit. Intensive cardiac unit, Intensive pulmonary care unit, Catheterization, Balloon Valvoplasty, Coronary stenting, Kidney Transplantation units with Haemodialysis machines and an assisted Reproductive Technology Centre.

DEPARTMENT SELECTED FOR STUDY IN THE HOSPITAL

The department selected for the study was general medicine department. The reason for selection of this department was that it had plenty of patients with different co morbid conditions being dealt with different class of antibiotics which is the actual requirement for the study. Pharmacy Practice Department provides services to the department and a good cooperation from the medical team added up to the reason for selecting this department for conducting the study.

CONSENT FROM HOSPITAL AUTHORITIES

The protocol of the study includes the scope of the study, objectives, methodology and outcome. The protocol was presented to the members of ethical committee for approval and the authorisation from the dean to carry out the study

was procured through his letter **[SRH/EC.5-9/2016-17 Dated February 2016]** and the same is attached for the reference in the **[Annexure 1]**. The study was conducted with the expert guidance of senior and junior physicians of the study department. The author was allowed to utilize the hospital facilities to make a follow up of the cases, in the selected department. The entire health care professionals were well informed through Dean's official circular.

LITERATURE SURVEY

Literature survey was carried out regarding the different aspects that should be considered while doing a study based on drug utilization of antibiotics. These include various drug utilization studies, prescribing patterns, identifying the adverse effects, sensitivity patterns, developing questionnaires and cost comparison studies. The literature supporting the study was gathered from various journals.

- **Study Site:** General Medicine Department
- **Study Design:** Prospective observational study
- **Study Duration:** 10 months (November – August)
- **Sample Size:** 150 patients

PATIENT SELECTION

- **Inclusion Criteria:** Patients of all age of either sex getting admitted in the study site during the study period, who have been prescribed with antibiotics and are willing to participate, are included in the study.

- **Exclusion Criteria:** Patients in which the antibiotics are not prescribed and those who are not willing to participate in the study are excluded.

PATIENT INFORMATION FORM

A patient information form was prepared to inform the patient or the care givers about the purpose and necessity of the study. The patients were assured that the confidentiality will be strictly maintained. The model of the information form is given in [**Annexure 2]** for the reference**.**

PATIENT CONSENT FORM

A patient consent form has been prepared and written consent was obtained from the caregivers. The format contains details like address, date, place, provision for signature of the patient or caregivers, investigator and supervisor. The same is given in the [**Annexure No. 2]** for reference.

DATA ENTRY FORMAT

A specially designed data entry format was used to enter all patient's details like patient name, age, sex, date of admission, date of discharge, reason for admission, past medical history, medication history, social history, vital signs like temperature, BP, and pulse.

Provision is given in the format to enter laboratory investigations like Blood sugar level(FBS,PPS,RBS),Blood counts (Hb, TLC,ESR, Platelet count, Clotting time, Bleeding time, Liver function test, Renal function test, Electrolytes, urine examination, Diagnosis, Co-morbidities associated, Drugs prescribed, Drug interactions, Adverse effects and any interventions.

METHOD

The data was collected during regular ward round participation in the department of General Medicine. Standard data entry format was used to enter all the patient details collected during ward rounds. The prescriptions were individually screened to assess the prescribing pattern of antibiotics. The DDD is

the assumed average maintenance dose per day for a drug used for its main indication in adults. DDD/100 bed-days (Defined Daily Dose) of 10 most commonly prescribed antibiotic was calculated. DDD/100 bed- days provides at estimate of consumption of drugs in general medicine department. And also ATC code of the antibiotics were recorded.

$$\text{DDD/100 bed-days} = \frac{\text{No. of units administered in a given period (mg)} \times 100}{\text{DDD (mg)} \times \text{no. of days in the period} \times \text{no. of beds} \times \text{occupancy index}}$$

The sensitivity patterns of the antibiotics were evaluated with the help of a suitable antibiogram provided from the microbiological laboratory.

The adverse effects of the antibiotics were monitored during drug administration and the information on any adverse effect of the drug experienced by the patient was gathered during the ward rounds and reported

The cost comparison of the antibiotics was assessed by analysing the prescribed brand of antibiotic in the hospital with the other brand of the same antibiotic which is available in the market. Cost of prescribed antibiotics and alternate antibiotics of same class were statistically analysed.

STATISTICAL ANALYSIS

In this study used SPSS (Statistical Package for the Social Sciences) was used to compare the cost of prescribed antibiotics to alternate antibiotics of same class. Other statistical tools like ANOVA and Chi Square were also used in the study

REPORT SUBMISSION

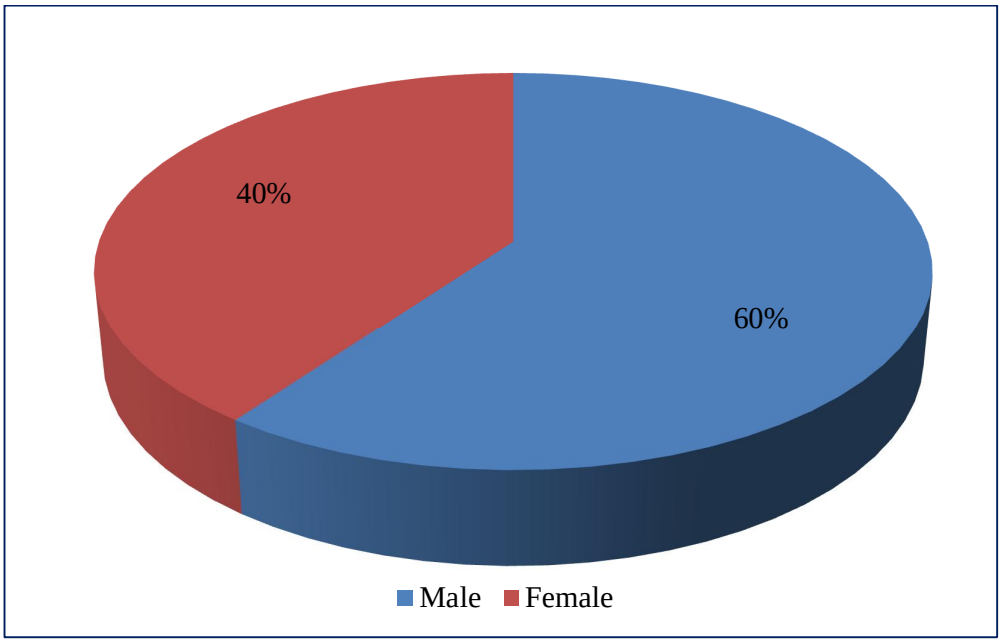
The reports on the study were prepared and the same was submitted to the study department.

RESULTS

TABLE No. 1: GENDER CATEGORIZATION

Sl. No.	Sex	No. of cases (n=150)	Percentage (%)
1.	Male	90	60
2.	Female	60	40

FIGURE No. 1: GENDERWISE CATEGORIZATION

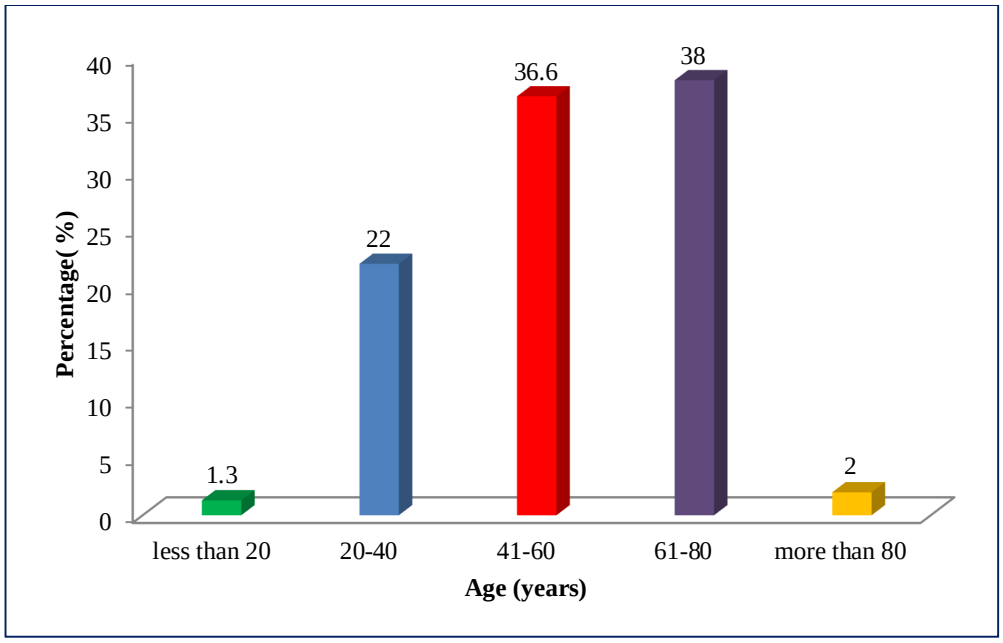


The study result shows that 60% of the patients were male and 40% were female.

TABLE No. 2: AGEWISE DISTRIBUTION

Sl.No.	Age	No. of patients prescribed (%) (n=150)	Percentage (%)
1.	< 20	2	1.3
2.	20 – 40	33	22
3.	41- 60	55	36.6
4.	61-80	57	38
5.	> 80	3	2

FIGURE No. 2: AGEWISE DISTRIBUTION

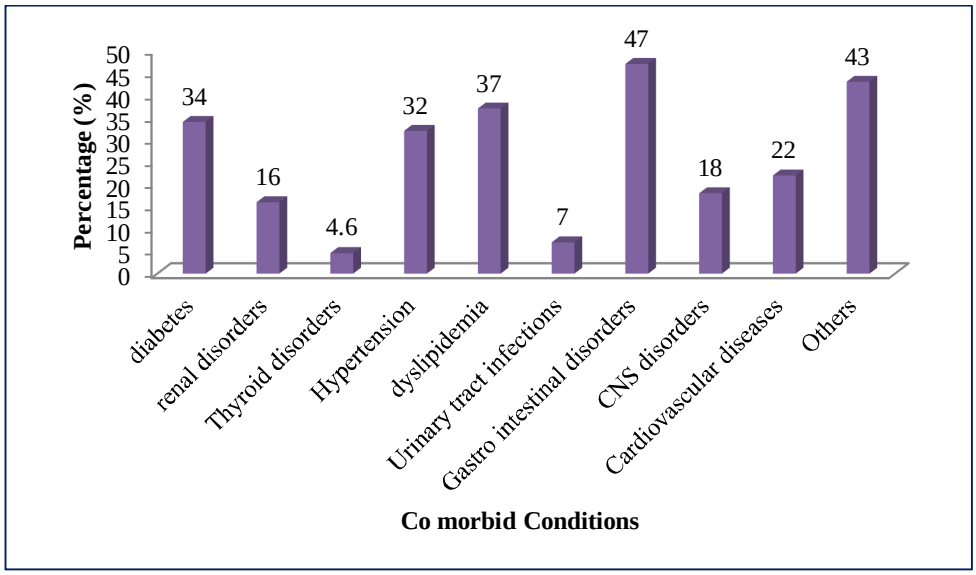


Agewise distribution of the patients were analysed and it was found that 1.3% of the prescriptions were in the age group of less than 20 years, followed by 22% in the age group of 20-40 years, 36.6% in the age group of 41-60 years, 38% in the age group of 61-80 years and 2% in the age group above 80 years.

TABLE No. 3: COMORBID CONDITIONS IN STUDY POPULATION

Disease condition	No. Of patients (%), n=150	Percentage (%)
Diabetes	51	34
Renal disorders	24	16
Thyroid disorders	7	4.6
Hypertension	48	32
dyslipidemia	37	24.6
Urinary tract infections	7	4.6
Gastro intestinal disorders	47	31.3
CNS disorders	18	12
Cardiovascular diseases	22	14.6
Others	43	28.6

FIGURE No. 3: COMORBID CONDITIONS

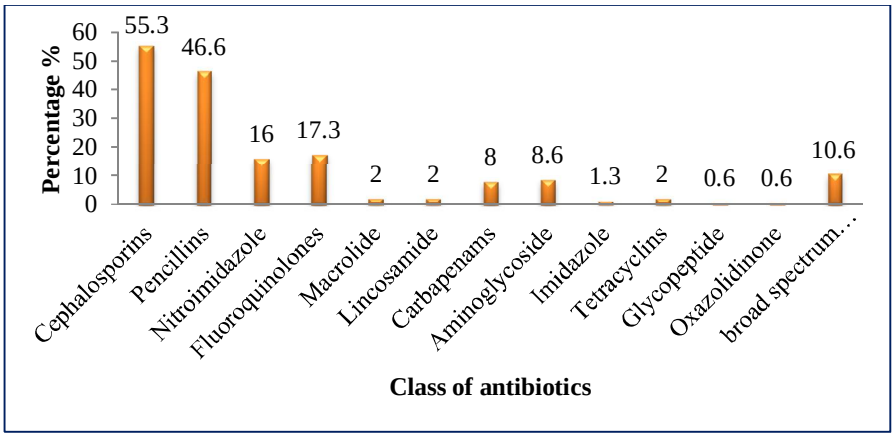


In the study on analysing co morbidities of study population it was noted that 34% were affected with diabetes followed by 16% with renal disorders, 4.6% with thyroid disorders, 32% with hypertension, 37% with dyslipidemia,7%with urinary tract infections, 47%with gastrointestinal disorders, 18%with CNS disorders and 22% of the patients with cardiovascular diseases.

TABLE No. 4: CLASS OF ANTIBIOTICS PRESCRIBED

Sl.No.	Antibiotic class	No. of prescription (n=150)	Percentage (%)
1.	Cephalosporins	83	55.3
2.	Pencillins	70	46.6
3.	Nitroimidazole	24	16
4.	Fluoroquinolones	26	17.3
5.	Macrolide	3	2.0
6..	Lincosamide	3	2.0
7.	Carbapenams	12	8.0
8.	Aminoglycoside	13	8.6
9.	Imidazole	2	1.3
10.	Tetracyclins	3	2.0
11.	Glycopeptide	1	0.6
12.	Oxazolidinone	1	0.6
13.	Broad spectrum antibiotic	16	16.0

FIGURE NO. 4:CLASS OF ANTIBIOTICS PRESCRIBED

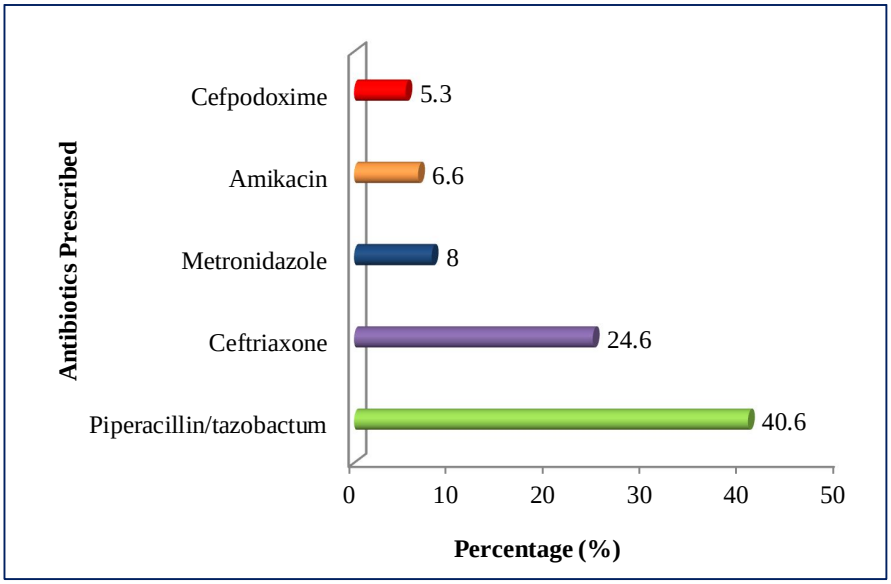


The study reports that the major class of antibiotics prescribed among patients were cephalosporins constituting about 55.3% followed by pencillins (46.6%), Nitroimidazole (16%), Fluoroquinolones (17.3 %), Macrolide (2%) lincosamide (2%) carbapenams (8%), aminoglycosides. (8.6%), midazole (1.3%), Tetracyclins (2%), Glycopeptide (0.6 %), Oxazolidinedione (0.6%) and Broad spectrum antibiotics about 10.6% in patients.

TABLE No. 5: COMMONLY PRESCRIBED ANTIBIOTICS

P	Antibiotics prescribed	No. of prescription(n=150)	Percentage(%)
1	Piperacillin/tazobactum	61	40.6
2	Ceftriaxone	37	24.6
3	Metronidazole	12	8
4	Amikacin	10	6.6
5	Cefpodoxime	8	5.3
6	Rifaximin	7	4.6
7	Ofloxacin	6	4
8	Ceftriaxone + tazobactum	4	2.6
9	Cefixime	4	2.6
10	Clarithromycin	3	2

FIGURE No. 5: COMMONLY PRESCRIBED ANTIBIOTICS

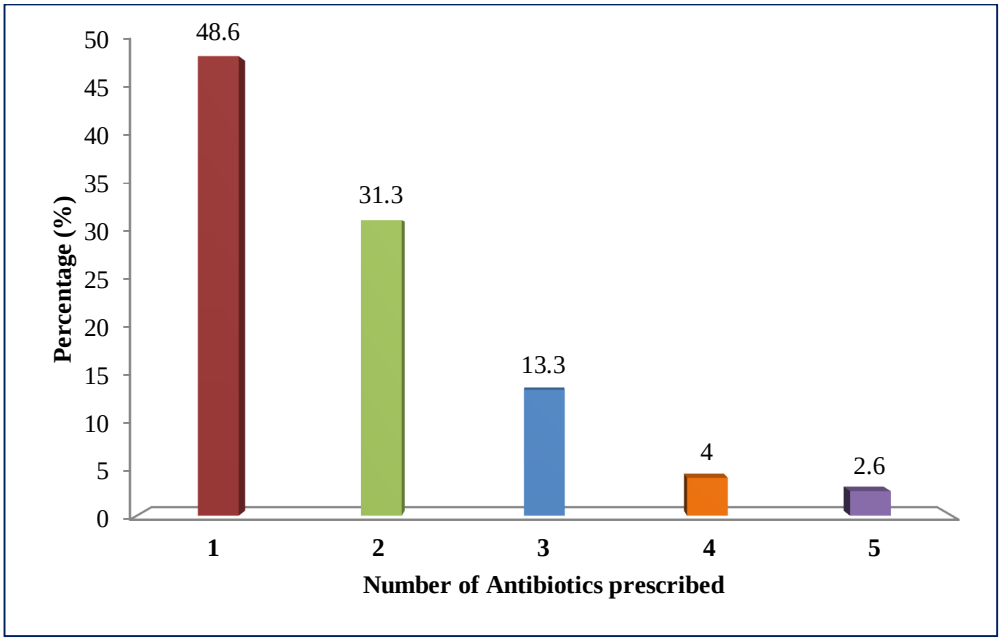


The study reports that 40.6% of the prescriptions were prescribed with piperacillin / tazobactum 24.6% with Ceftrixone,8% with Metronidazole,6.6% with Amikacin and 5.3% of the prescriptions were prescribed with Cefpodoxime .

TABLE No. 6: NUMBER OF ANTIBIOTICS PRESCRIBED (N=150)

S.No.	No. of antibiotics	No. of patients prescribed	Percentage (%)
1.	1	73	48.6
2.	2	47	31.3
3.	3	20	13.3
4.	4	6	4
5.	5	4	2.6

FIGURE No. 6: NUMBER OF ANTIBIOTICS PRESCRIBED

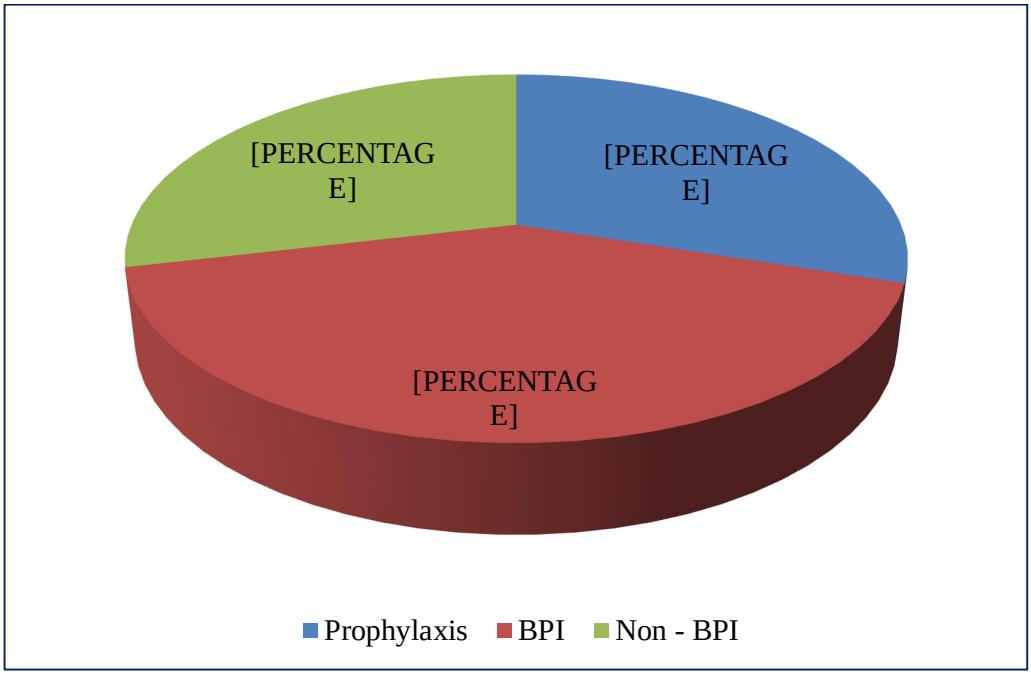


During the hospital stay, most of the patients were prescribed with only one antibiotic i.e. 73 patients, 47 patients with 2 antibiotics, 20 patients with 3 antibiotics, 6 patients with 4 antibiotics and only 4 patients were prescribed with 5 antibiotics.

TABLE No. 7: REASON FOR ANTIBIOTIC PRESCRIPTION (N=150)

Sl.No.	Antibiotic prescribed for	No. of patients prescribed	Percentage (%)
1.	Prophylaxis	45	30
2.	BPI	62	41
3.	Non- BPI	43	29

FIGURE No. 7: REASON FOR ANTIBIOTIC PRESCRIPTION

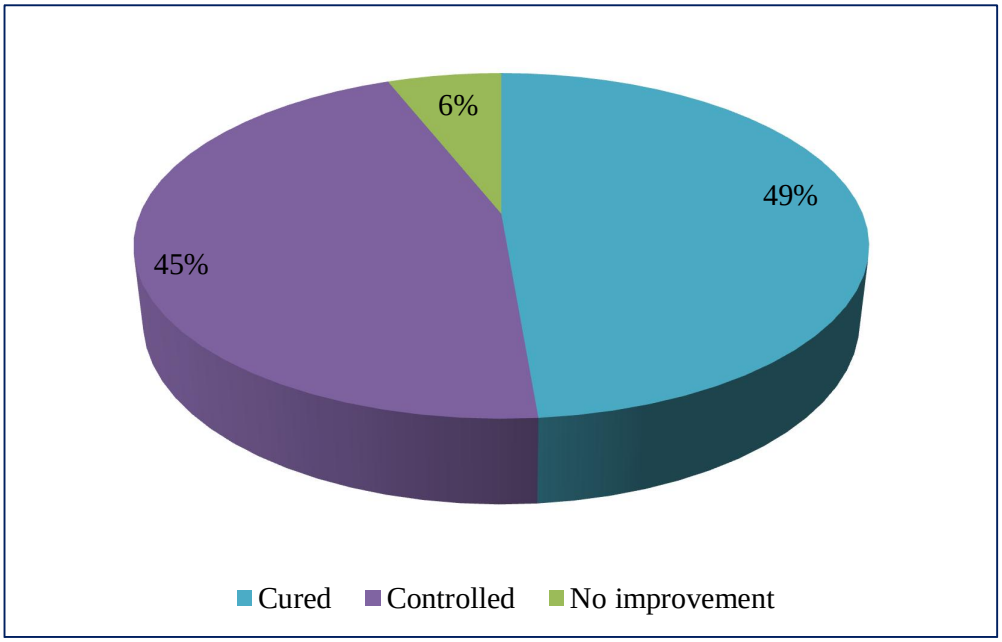


The study shows that 41% of the patients were prescribed with antibiotics for Bacteriologically Proven Infection (BPI) followed by 29% of patients for Non Bacteriologically Proven Infection (Non-BPI) and 30% of the patients for prophylaxis.

TABLE No. 8: THERAPEUTIC OUTCOMES OF ANTIBIOTICS

Sl.No.	Therapeutic outcomes	No. of patients prescribed (n=150)	Percentage (%)
1.	Cured	73	49
2.	Controlled	68	45
3.	No improvement	9	6

FIGURE No. 8: THERAPEUTIC OUTCOMES OF ANTIBIOTICS



The therapeutic outcomes of antibiotics among patient's reports that around 49% of the patients were completely cured by the therapy and about 45 % of the patients showed controlled response on therapy and around 6% of the patients had no improvement.

Table No. 9: FACTORS AFFECTING THE NUMBER OF ANTIBIOTICS PRESCRIBED (n=150)

			No. of Antibiotics			p value
		n	1 Antibiotics	2 Antibiotics	> 2 Antibiotics	
Gender	Male	90	46	23	21	0.248
	Female	60	29	22	9	
Age	< 20	3	1	1	1	0.850
	21-40	33	16	9	8	
	41-60	55	27	17	11	
	61-80	56	28	18	10	
	> 80	3	3	0	0	
Duration of stay	< 5 days	43	28	9	6	0.015*
	5 days	23	11	11	1	
	> 5 days	84	36	25	23	

P<0.05 is considered significant

In the study number of antibiotics prescribed was compared with gender, age and duration of treatment and it was found that most of patients were prescribed with one antibiotics. In comparison to gender, 46 males were prescribed with single antibiotics whereas only 29 females were prescribed with single antibiotics. When compared to age groups most of patients in age group of 41-60 and 61 -80 were prescribed with single antibiotic during the study. The study reports that only duration of stay was found to be statistically significant (p= 0.015).

FIGURE NO.9: DURATION OF STAY WITH NUMBER OF ANTIBIOTICS PRESCRIBED

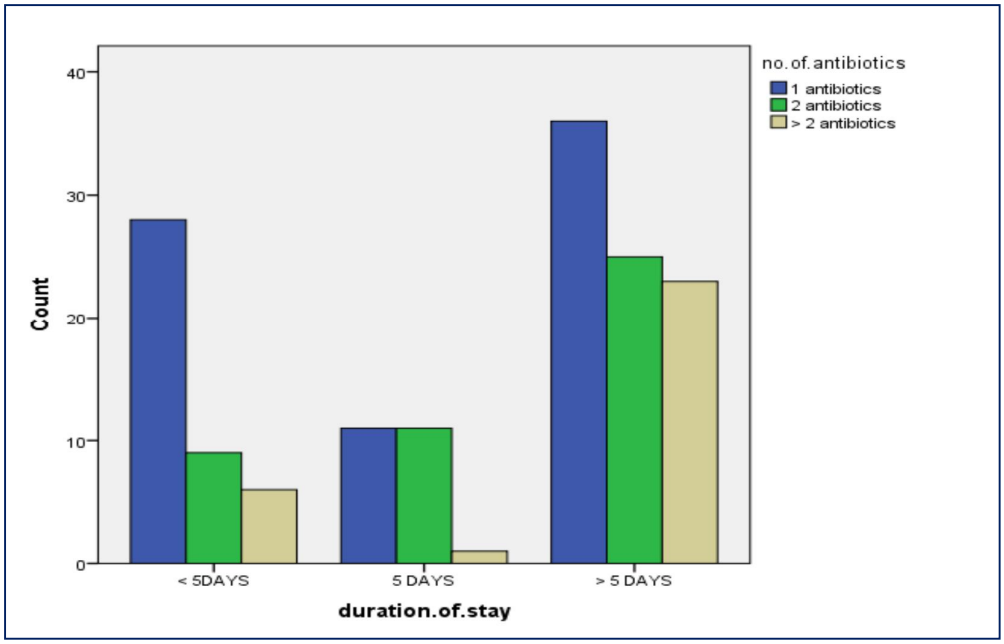


TABLE No.10: DDD/100 BED- DAYS AND ATC CODE OF ANTIBIOTICS

Sl.No.	Name of Antibiotics	DOSE	DDD/100 bed- days	ROA	ATC code
1	Piperacillin/tazobactum	4.5 gm	0.2269	IV	J01CR05
2	Ceftriaxone	1.0gm	0.35	IV	J01DD04
3	Metronidazole	500mg	0.026	IV	J01XD01
4	Amikacin	500mg	0.0175	IV	J01GB06
5	Cefpodoxime	100mg	0.007	Oral	J01DD13
6	Rifaximin	400mg	0.0105	Oral	A07AA11
7	Ofloxacin	200mg	0.007	IV	J01MA01
8	Ceftriaxone + tazobactum	1.0gm	0.0701	IV	J01DD54
9	Cefixime	200mg	0.0224	Oral	J01DD08
10	Clarithromycin	500mg	0.0087	Oral	J01FA09

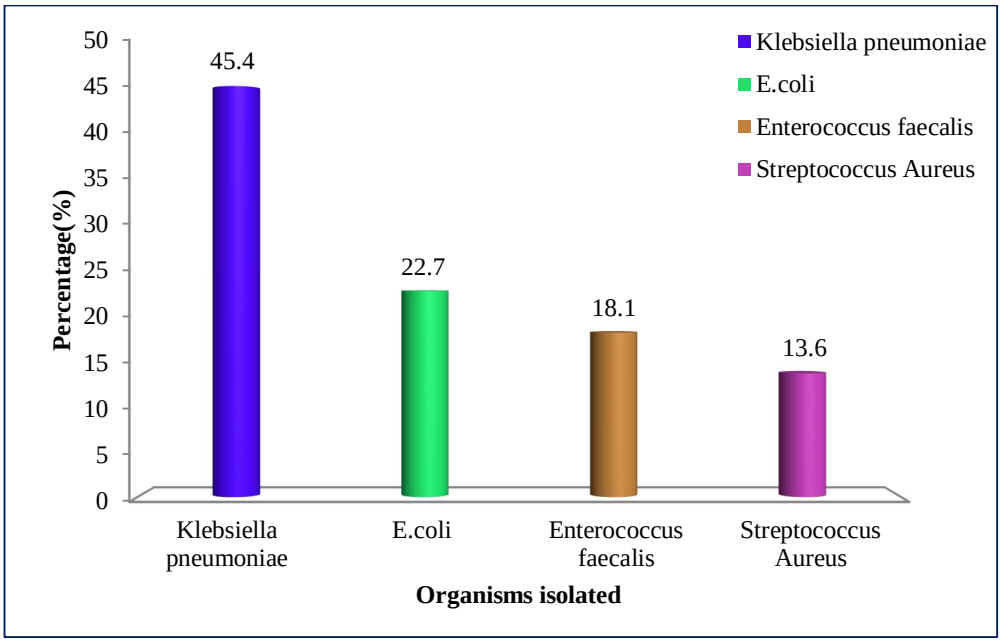
In the study DDD/100 bed – days of the 10 most common antibiotics was calculated. . In the study the antibiotic use was found to be 0.7461 DDD/ 100 beds- days. The study was carried out for a period of 180 days and average occupancy index was 0.72. The 10 most common antibiotics were classified using the Anatomical Therapeutic Chemical (ATC) Classification given by WHO International Working Group for Drug Statistics Methodology. The main purpose of this classification is for international drug utilization research and for adverse drug reaction monitoring.

SENSITIVITY PATTERN OF ANTIBIOTICS

TABLE No. 11: ORGANISMS ISOLATED

Sl.no	Organism	Number of patients (n=22)	Percentage (%)
1	*Klebsiella Pneumonia*	10	45.4
2	*E.Coli*	5	22.7
3	*Enterococcus Faecalis*	4	18.1
4	*Streptococcus Aureus*	3	13.6

FIGURE No. 11: ORGANISMS ISOLATED

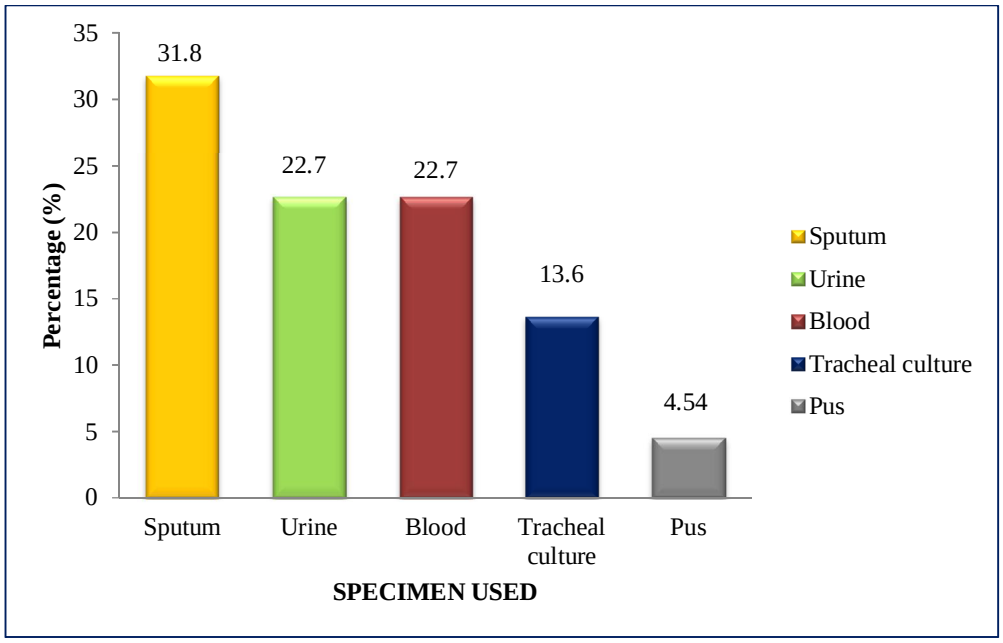


The study shows different strains of organisms that were isolated from the patients culture test .Among the isolated organisms the most common were *Klebsiella pneumoniae* 45.4%, followed by *E.coli* 22.7%, *Enterococcus faecalis* 18.1% and *Strep. aureus* 13.6% were reported in the culture samples.

TABLE No. 12: SPECIMEN SAMPLE USED FOR CULURE SENSITIVITY

Sl.no	Specimen used	Number of patients (n=22)	Percentage (%)
1	Sputum	7	31.8
2	Urine	5	22.7
3	Blood	5	22.7
4	Tracheal culture	3	13.6
5	Pus	1	4.54

FIGURE No. 12 SPECIMEN SAMPLE USED FOR CULURE SENSITIVITY

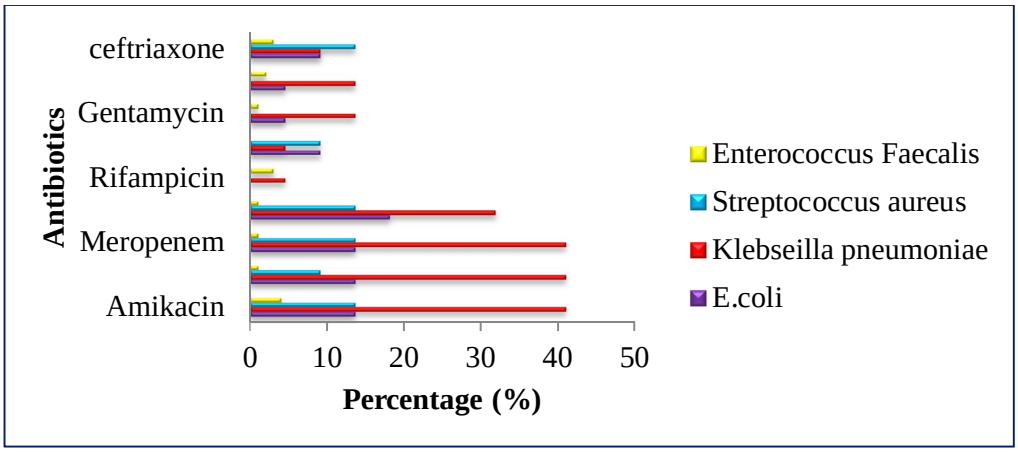


The specimen samples used in the culture sensitivity was Sputum 31.8%, Urine 22.7%,Blood 22.7%, Tracheal Culture 13.6% and Pus 4.54%.

TABLE NO. 13: SENSITIVITY PATTERN TOWARD VARIOUS ANTIBIOTICS

ORGANISM	DRUG SENSITIVITY								
	Amikacin	Imipenem	Meropenem	Piperacillin/ tazobactum	Rifampicin	Co-trimamoxazole	Gentamycin	Ofloxacin	Ceftriaxone
Klebsiella pneumoniae	9	9	7	1	1	3	3	1	1
E.coli	3	3	3	4	-	2	1	1	2
Enterococcus faecalis	1	1	1	3	-		3	3	-
Staphylococcus aureus	2	3	3	-	1	2	-	-	3

FIGURE No. 13: SENSITIVITY PATTERN TOWARD VARIOUS ANTIBIOTICS



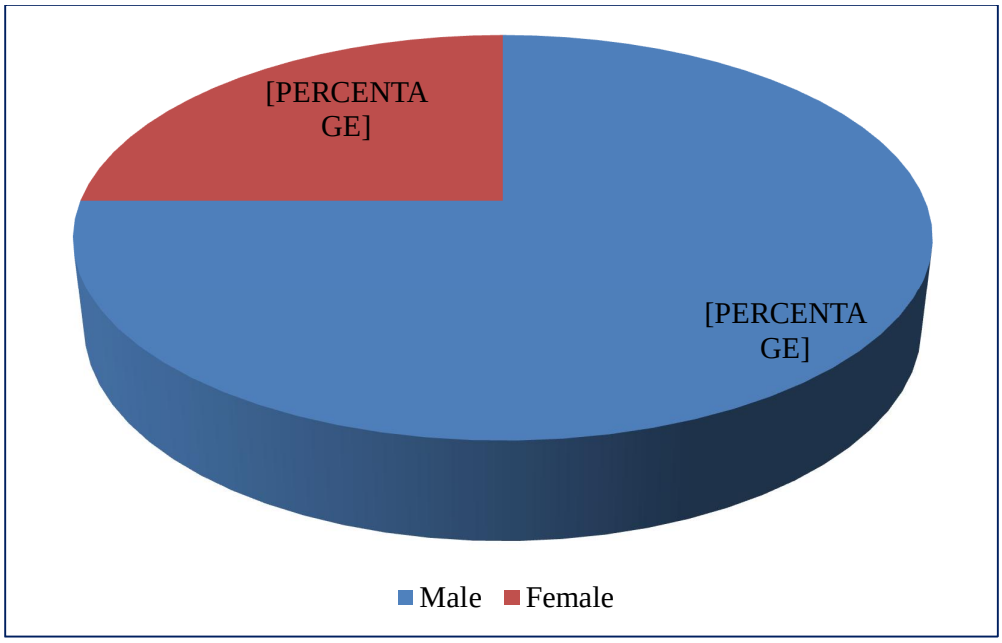
In the study 22 cases were subjected to antibiotic sensitivity studies, which revealed that K. pneumonia were higly sensitive to Amikacin and Imipenem, E. coli were sensitive to piperacillin/ tazobactum, E. faecalis were sensitive to piperacillin/ tazobactum, Gentamycin and Ofloxacin, S. aureus were sensitive to Imipenem, Meropenam and Cefriaxone.

TABLE NO. 14: ADR BASED ON GENDER

Sl No.	Sex	No. of ADR(n=12)	Percentage

1.	Male	9	75
2.	female	3	25

FIGURE No. 14: ADR BASED ON GENDER



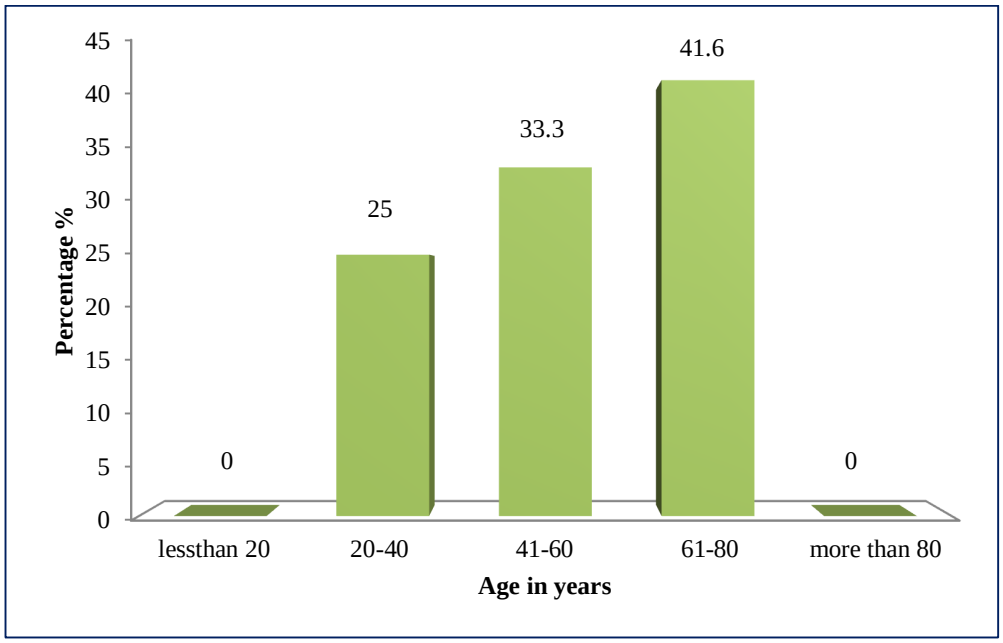
The study reports revealed that the adverse drug reactions(ADR) are found to be more prone among males constituting to about 75% of the patients and to about 25% in female patients.

Sl.No.	Age	No. of ADR(n=12)	Percentage (%)

1.	< 20	0	0
2.	20 – 40	3	25
3.	41- 60	4	33.3
4.	61-80	5	41.6
5.	> 80	0	0

TABLE No. 15: ADR BASED ON AGE GROUP

FIGURE No. 15: ADR BASED ON AGE GROUP



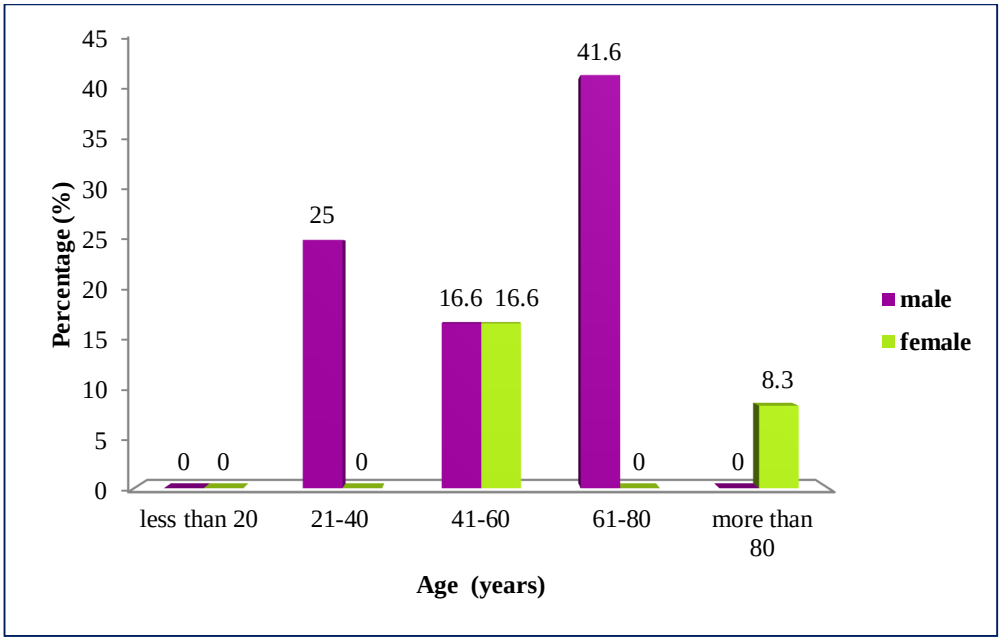
Adverse drug reactions based on age group showed that the patients who were at an age group of 61-80 years were mostly affected to about 41.6% followed by 41-60 years at 33.3 % and patients at an age group 20-40 years were least affected by the adverse reactions to antibiotics which constituted to only about 25%.

TABLE No. 16: AGE AND GENDER WISE DISTRIBUTION OF ADR

Sl.	Age	Male	Female	Total no. of ADR	Percentage

No.				(n=12)	(%)
1	< 20	0	0	0	0
2	20 – 40	3	0	3 (16.6%)	16.6
3	41- 60	2	2	4 (33.3%)	33.3
4	61-80	5	0	5 (41.6%)	41.6
5	> 80	0	1	1 (8.3 %)	8.3

FIGURE No. 16: AGE AND GENDER WISE DISTRIBUTION OF ADR



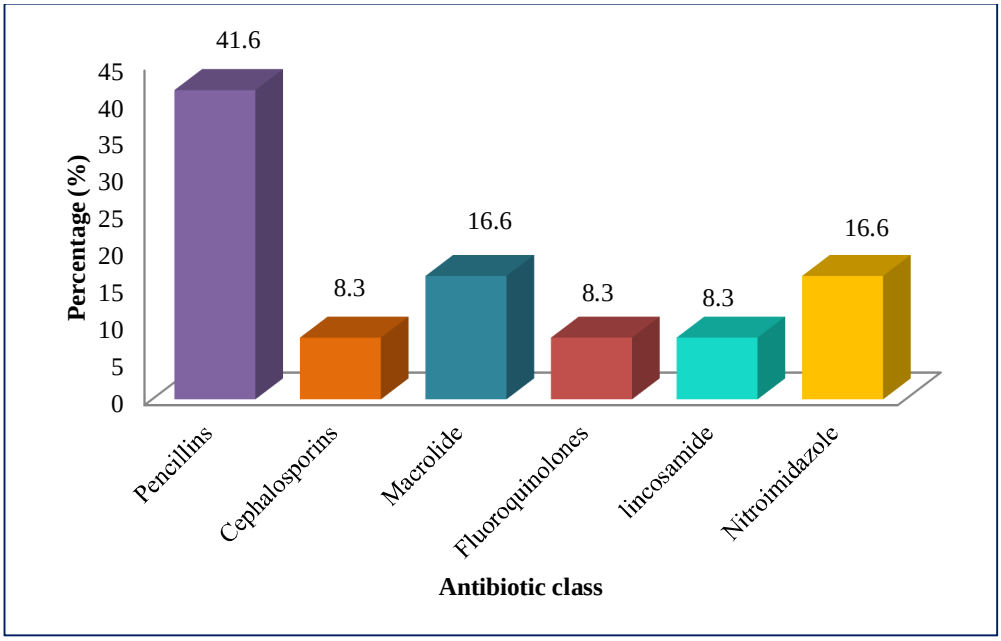
The age and gender wise distribution of ADR showed that 41.6% of male patients in the age group of 61-80 were more affected , followed by 25% of male patients in the age group of 20-40 were affected. In the age group of 41-60 both male and female were equally prone to the reaction to about 16.6%. About 8.3% of the female patients were affected in the age group of more than 80 years.

TABLE No. 17: CLASS OF ANTIBIOTICS CAUSING ADR

Sl No.	Antibiotic class	No. of ADR (n=12)	Percentage (%)

1	Pencillins	5	41.6
2	Cephalosporins	1	8.3
3	Macrolide	2	16.6
4	Fluoroquinolones	1	8.3
5	lincosamide	1	8.3
6	Nitroimidazole	2	16.6

FIGURE No. 17: CLASS OF ANTIBIOTICS CAUSING ADR



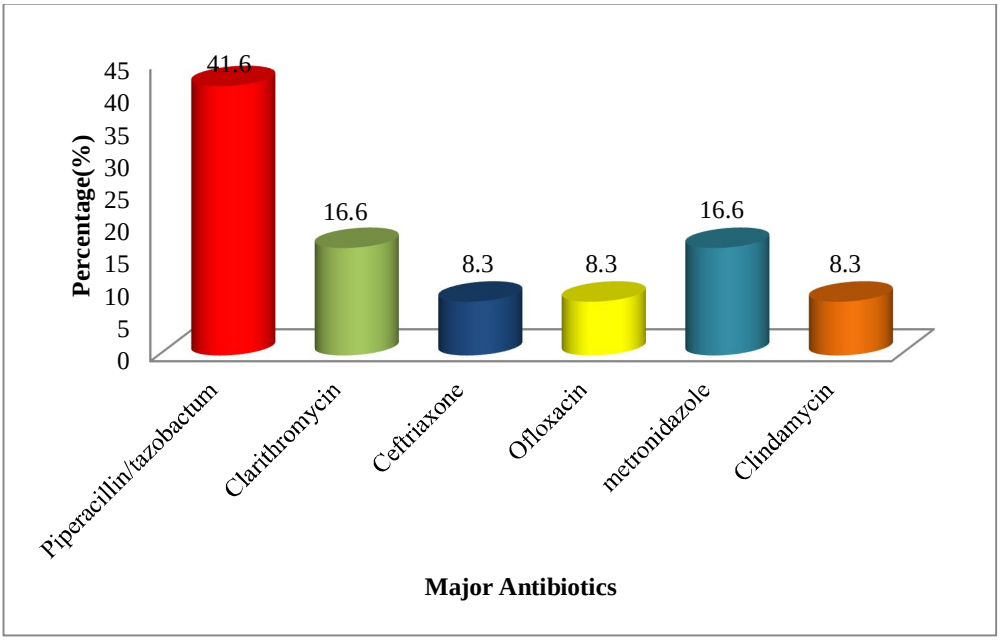
The major class of antibiotics causing adverse drug reactions in patients were found to be Pencillins (41.6%), followed by Cephalosporins (16.6%), Macrolide (16.6%), Fluoroquinolones (8.3 %), Lincosamide (8.3%) and Nitroimidazole (16.6%) were being reported in the study.

TABLE No.18: ANTIBIOTICS CAUSING ADR

Sl.No.	Name Of Drug	No. of ADR	Percentage (%)

		(n=12)	
1	Piperacillin/tazobactum	5	41.6
2	Clarithromycin	2	16.6
3	Ceftriaxone	1	8.3
4	Ofloxacin	1	8.3
5	Metronidazole	2	16.6
6	Clindamycin	1	8.3

FIGURE No. 18: ANTIBIOTICS CAUSING ADR



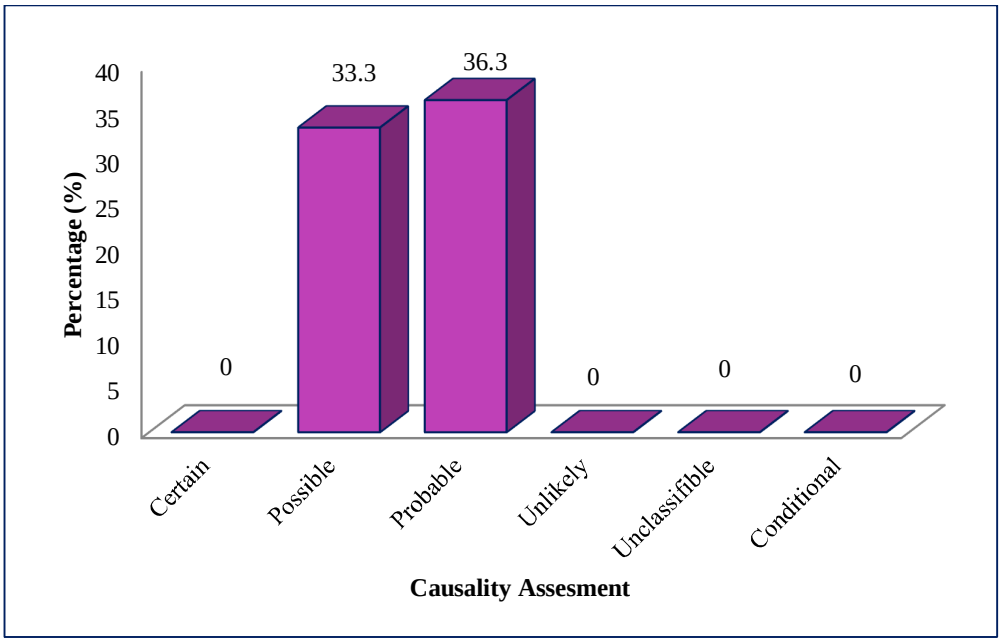
The major antibiotics causing adverse drug reactions in patients were found to be Piperacillin/Tazobactum in 41.6%,followed by Clarithromycin in16.6% ,Ceftriaxone in 8.3% , Ofloxacin in 8.3 % , Metronidazole in 16.6% and Clindamycin in 8.3% of the patients were being reported in the study.

TABLE No. 19: CAUSALITY ASSESSMENT

Sl.No	Causality assessment	No. of ADR	Percentage

		(n=12)	(%)
1	Certain	0	0
2	Possible	4	33.3
3	Probable	8	36.3
4	Unlikely	0	0
5	Unclassifible	0	0
6	Conditional	0	0

FIGURE No. 19: CAUSALITY ASSESMENT



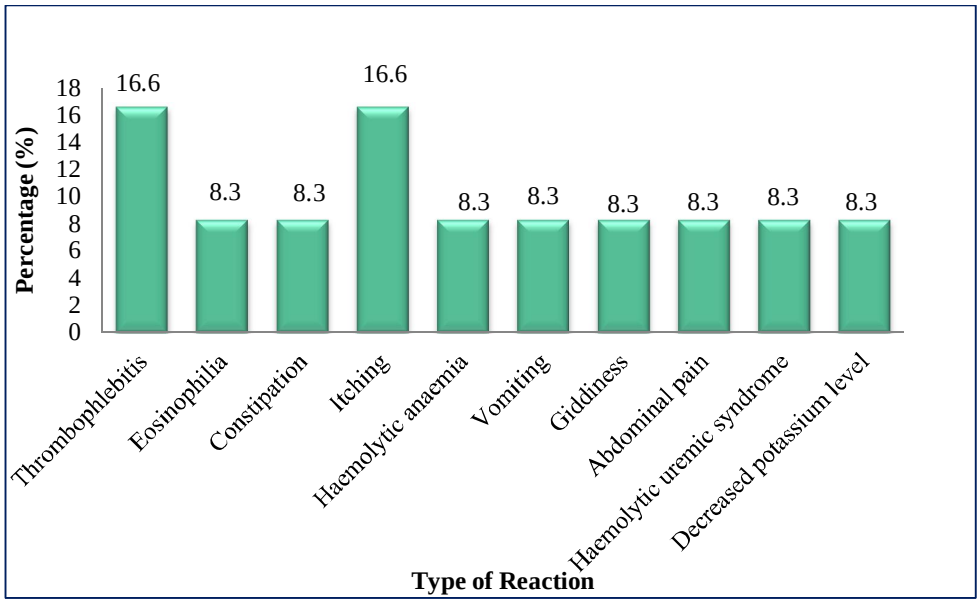
The adverse drug reactions assessment by WHO causality assessment scale showed that around probable ADR's counted for 36.3% and possible ADR's counted for 33.3% among the patients.

TABLE No. 20: REACTION OBSEREVED DURING ADR

Sl No.	Type of reaction	No. of ADR (n=12)	Percentage %
1	Thrombophlebitis	2	16.6

2	Eosinophilia	1	8.3
3	Constipation	1	8.3
4	Itching	2	16.6
5	Haemolytic anaemia	1	8.3
6	Vomiting	1	8.3
7	Giddiness	1	8.3
8	Abdominal pain	1	8.3
9	Haemolytic uremic syndrome	1	8.3
10	Decreased potassium level	1	8.3

FIGURE No. 20: REACTION OBSERVED DURING ADR



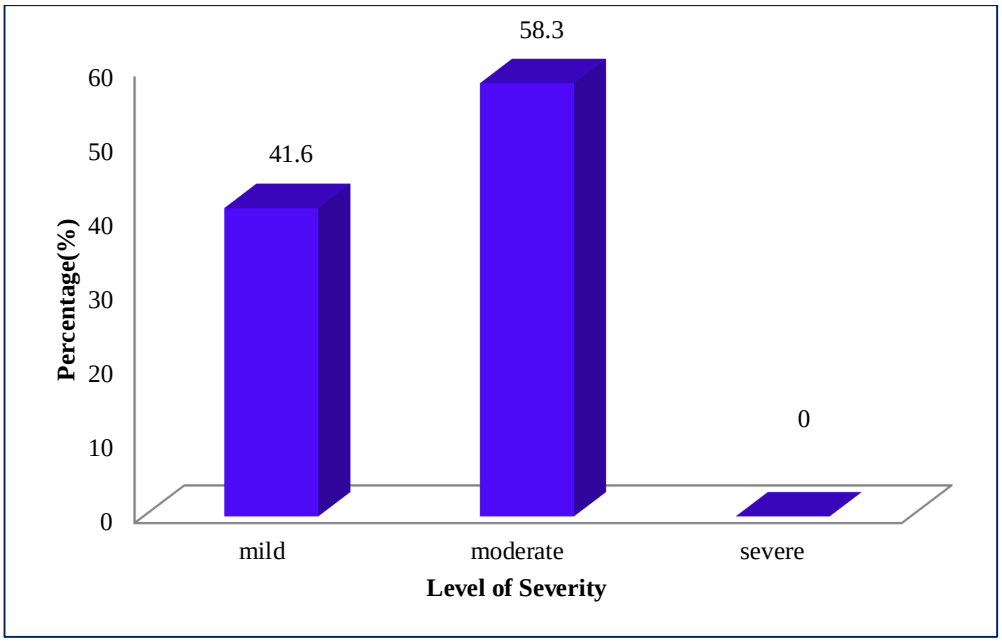
The reactions seen in patients were Thrombophlebitis in 16.6%, Eosinophilia in 8.3%, Constipation in 8.3%, Itching in 16.6%, Haemolytic anaemia in 8.3%, Vomiting in 8.3%, Giddiness in 8.3%, Abdominal pain in 8.3%, Haemolytic uremic syndrome in 8.3% and Decreased potassium level in 8.3% patients were being reported.

TABLE No. 21: ADR BASED ON LEVEL OF SEVERITY (N=12)

Sl.No.	Level of severity	No. of ADR	Percentage (%)
1	Mild	5	41.6

2	Moderate	7	58.3
3	Severe	0	0

FIGURE No. 21: ADR BASED ON LEVEL OF SEVERITY



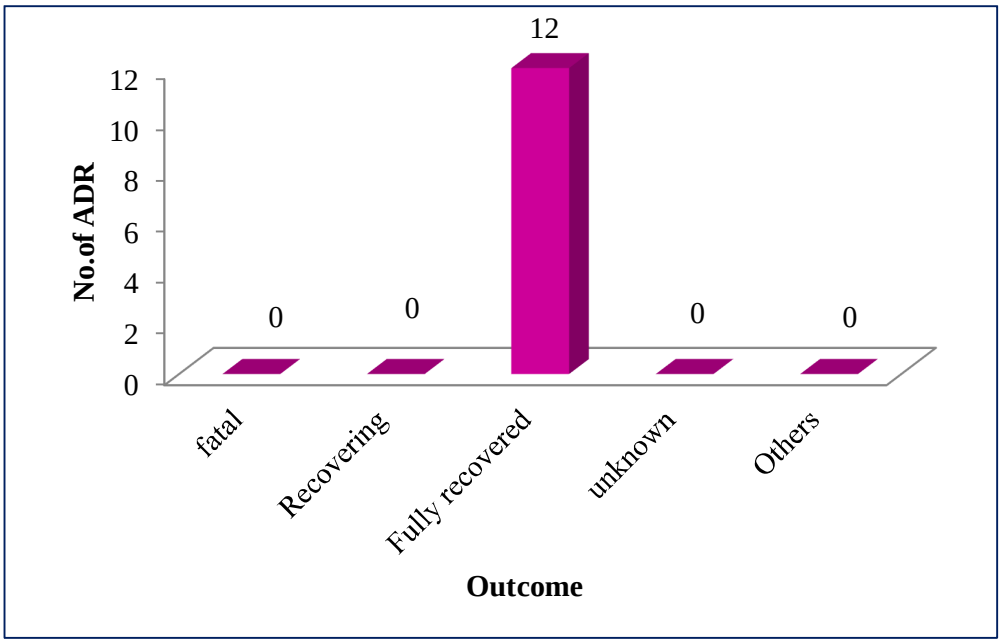
Based on the level of severity, Mild reactions constituted to about 41.6%, Moderate reactions to about58.3% and no severe reactions were observed or reported in patients.

TABLE No. 22: OUTCOMES (N=12)

Sl.No.	Outcome	No. of ADR
1.	Fatal	0

2.	Recovering	0
3.	Fully recovered	12
4.	Unknown	0
5.	Others	0

FIGURE 22: OUTCOMES



In the study all ADR among the patients were fully recovered during the hospital stay.

TABLE 23: COST COMPARISON OF ANTIBIOTICS (N=150)

		n	Cost of antibiotics Mean ±S.D.	p value	Alternate cost Mean ±S.D.	p value

Gender	Male	90	2014.31±2199.70	0.636	1189.49±1320.03	0817
	Female	60	1841.77±2152.65		1139.83±1233.23	
Age	< 20	3	1941.68±2043.03	0.883	1159.65±819.02	0.980
	21-40	33	1872.19±1950.19		1055.33±833.79	
	41-60	55	2144.59±2481.09		1220.00±1371.73	
	61-80	56	1843.45±2067.70		1198.11±1458.78	
	> 80	3	1000.23±970.46		981.66±984.19	
Duration of stay	< 5 days	43	1824.94±2394.95	0.323	1170.29±1503.86	0.612
	5 days	23	1412.87±1841.76		933.27±1215.11	
	> 5 days	84	1945.29±2175.39		1234.01±1181.16	
Total		150	1945.29±2175.39	<0.001	1169.63±1282.04	< 0.001

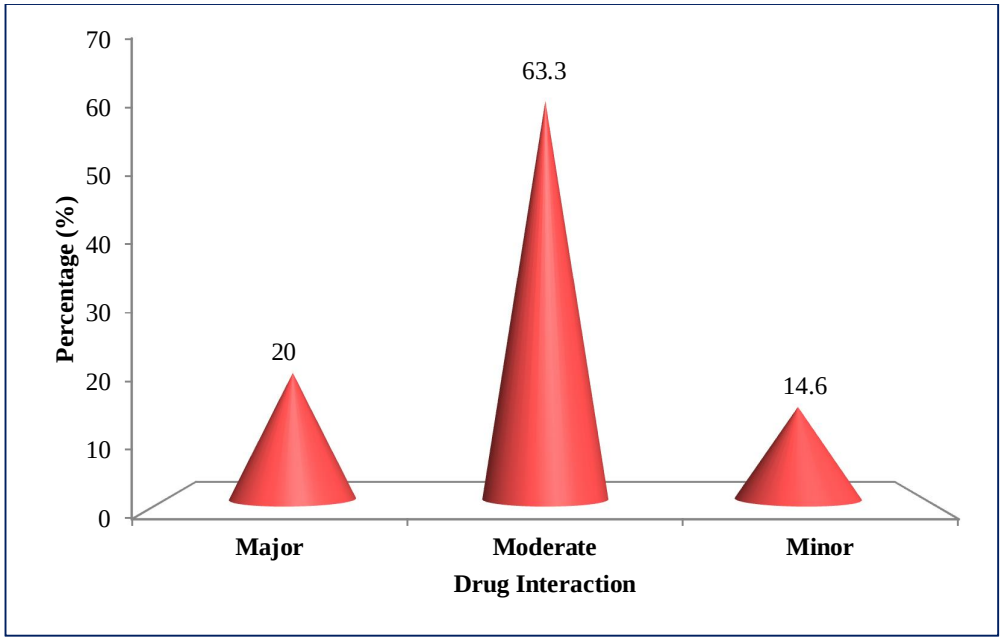
In the study cost of antibiotics prescribed and cost of alternate antibiotics were calculated. The total cost was Rs.1945.29±2175.39 whereas for alternate antibiotics Rs. 1169.63±1282.04. In comparison to gender, males had more cost for antibiotics than females. Cost of antibiotics was also compared with age and duration of stay and by comparing mean value of cost and alternate of antibiotics, latter had less cost than former antibiotics prescribed.

TABLE NO: 24 DRUG INTERACTIONS (N=150)

Severity	No. of Patients	Percentage (%)
Major	30	20
Moderate	95	63.3

Minor	25	14.6

FIGURE NO: 24 DRUG INTERACTIONS



The severity of drug interactions were evaluated and categorized into major, moderate and minor type interactions. It was observed that 65% of the interactions had moderate severity 20% of the interactions had major severity and 15% come under minor interactions.

DISCUSSION

The current study on gender categorization had revealed that the overall study population was predominantly male population. In a similar study conducted by **Ravi Pathiyil Shankar et al (2003)** [15] also noted that majority of patients were males. Age wise distribution was analysed and found that most of the prescription were in the age group of 61-80 years followed by 41-60 years. Similar study conducted by **Mujtaba Hussain et al (2014)** [8] also found that most of prescription were in age group of 46-60 years. In the present study, categorization based on co morbid conditions was analysed and found that most of the patients were having gastrointestinal disorders which was similar to a study conducted by **Mohanraj Rathinavelu et al (2015)**[2] who reported that majority of patients had urinary tract infection.

The current study reports on major class of antibiotics prescribed among patients were Cephalosporins followed by Penicillins. This study was similar to a study conducted by **Venu Gopal D et al (2014)**[6] also found that cephalosporins were mostly prescribed to inpatients and Penicillin usage was found to be maximum in outpatients. The most commonly prescribed antibiotic was piperacillin / tazobactum (40.6%) followed by ceftriaxone (24.6%) during the hospital stay which could be compared to a similar study conducted by **Meher B. R et al (2014)**[9]**.** During the study most of the prescription had single antibiotics prescribed (48.6%), which was similar to a study conducted by **R Selvaraj et al (2015)**[1].

The current study reports that majority of the antibiotics were prescribed for BPI, which was similar to a study conducted by **Ravi Pathiyil Shankar et al (2003)**[15] also found that most of patients were prescribed antibiotics for BPI.

Reports on therapeutic outcomes during the hospital stay shows that 49% of the patients were completely cured by the therapy and about 45 % of the

patients showed controlled response on therapy and around 6% of the patients had no improvement. A similar study was observed by **Shalem Lakkepogu et al (2014)[40]** also noted majority of patients were cured and only some patients didn't show any response.

The reports on number of antibiotics prescribed and duration of stay was found statistically significant (p= 0.015). A similar study conducted by **Aparna Williams et al (2011)[47]** also compared number of antibiotics prescribed with gender, age and duration of treatment and revealed that there was statistically significance between number of antibiotics prescribed and duration of stay in hospital.

In the present study DDD/100 bed – days of the 10 most common antibiotics was calculated. The antibiotic use was found to be 0.7461 DDD/ 100 beds- days and the drug piperacillin/tazobactum use was high as the dose of this drug used in our hospital site was high when compared to WHO recommended DDD. Our study was compared with the study conducted by **Mohanraj Rathinavelu et al(2015)[2]** analysed DDD/100 bed- days and ATC code of 10 commonly used antibiotics was calculated and the drug Nitrofurantoin use was high as the dose of this drug used in study site was high when compared to WHO recommended DDD.

The organisms commonly seen in the study were *Kbleseilla pneumoniae*, followed by *E.coli*, *Enterococcus Faecalis* and *Streptococcus aureus* which were similar to the study conducted by **Ravi Pathiyil Shankar et al (2003)[15]** were the most common organism isolated was *H. Influenzae, E. coli, K. pnemoniae, S.aureus.*In the present study inorder to analyse the sensitivity pattern of antibiotics, specimen samples used in the culture consist of Sputum, Urine, Blood, Tracheal Culture and Pus. The sensitivity pattern of the antibiotics were analysed and the reports were found to be similar with the study conducted by **Bijoy Thomas et al (2014)[24]** for reporting antibiotics sensitivity pattern using

urine, trachea, pus, sputum, throat swab. In a similar study conducted by **Bijoy Thomas et al (2014)**[24] the sensitivity pattern data revealed that E. coli were highly sensitive to Amikacin, followed by Klebsiella to Amikacin, and Pseudomonas to Meropenem

In the present study 12 ADRs were observed. On gender wise distribution the study revealed that the adverse drug reactions are found to be more prone among male patients. In study conducted by **M. Shamna et al (2014)**[7] also found males were more predominant than females in ADR occurrence. In the present study most of adverse drug reactions (ADR) were at an age group of 61-80 years (41.6%). A similar study conducted by **Farhan Ahmad Khan et al (2013)** [50] also found that most of ADR were reported in age group of 61-80 years. The current study showed that majority of ADR were reported in antibiotic class of Pencillins which was similar to a study conducted by **Kavita Dhar et al (2015)**[51] noted that most ADR were reported by ceftriaxone and therapeutic Class of Antibiotics Implicated to cause ADR were beta lactams.

An assessment of ADR by WHO causality assessment scale showed both probable and possible ADR among the patients which was similar to a study conducted by **Kavita Dhar et al (2015)** [51] also showed that majority of ADR were probable and possible commonly seen ADR in the study were Thrombophlebitis and Itching which was similar to a study conducted by **R. Priyadharsinai et al (2011)**[49] observed rashes and urticaria as most commomly seen ADR pattern in their study. In the present study all ADR among the patients were fully recovered during the hospital stay which was similar to a study conducted by **D.Yadav et al (2015)** [48] also noted that most patients were recovered.

In the present study cost of antibiotics prescribed and cost of alternate antibiotics were calculated. The total cost was Rs. 1945.29±2175.39 for the prescribed antibiotics whereas for alternate antibiotics the cost was

Rs. 1169.63±1282.04. In comparison to gender, males had more cost for antibiotics than females. Cost of antibiotics was also compared with age and duration of stay and by comparing mean value of cost and alternate of antibiotics, latter had less cost than former antibiotics prescribed, which could be compared with a study conducted by **Aparna Williams et al (2011)**[47] the average cost of the antibiotics was Rupees 1995.08 (± SD 2099.99) per patient and antibiotics expenditure accounted for 73.2% of the total drug cost.

The study on the drug interactions shows that 63.3% of prescriptions had moderate drug interactions followed by major and minor interactions.

CONCLUSION

The current study could assess the prescribing pattern of antibiotics, pattern of antibiotic sensitivity, adverse effects of antibiotics prescribed and cost comparison of antibiotics. Most commonly prescribed antibiotic in the study population was Piperacillin / tazobactum followed by Ceftriaxone. The antibiotic sensitivity pattern revealed that Klebsiella pneumonia was highly sensitive to Amikacin and Imipenem, E. coli was sensitive to Piperacillin/ tazobactum, Enterococcus faecalis was sensitive to Piperacillin/ tazobactum, Gentamycin and Ofloxacin, Streptococcus aureus was sensitive to Imipenem, Meropenam and Ceftriaxone. The commonly observed ADR in the study population were Thrombophlebitis, Eosinophilia, Constipation, Itching, Haemolytic anaemia, Vomiting, Giddiness, Abdominal pain, Haemolytic Uraemia and decreased potassium level, these ADR's can be prevented by proper monitoring during drug administration and through educating the healthcare professionals regarding commonly occurring ADR'S. The cost analysis reports that the cost of prescribed antibiotics was high which costed Rs. 1945.29±2175.39 and which can be reduced by prescribing alternate antibiotics at a lower cost at Rs. 1169.63±1282.04 which would help in minimising the patient's expenditure. The drug interactions can be minimized by screening the prescription with micromedex drug database before dispensing.

Clinical pharmacists and Clinicians need to play vital role in minimizing the antibiotic problems by conducting continual awareness programs regarding up-to-date prescribing guidelines in the hospital and also minimizing the antibiotic resistance. The active participation of clinical Pharmacists in the clinical ward rounds and documentation of Pharmacist observation on prescription in patient folder is highly recommended for safety and drug monitoring.

Also physicians must have a clear understanding of rational therapeutic use of antibiotics. They must be aware of the prevalence of various pathogens and resistance patterns in their hospital and exercise good judgment in selection of the antibiotic regimens. Irrationality can be addressed by use of guidelines, educational activities and surveillance at all level of health care. So, measures should be taken to avoid the inappropriate use of antibiotics. Drug utilization review programme must be carried out to study the rational use of antimicrobials.

The rational use of antimicrobial agents is one of the main contributors to control worldwide emergence of antibacterial resistance, side effects and reduced cost of the treatment.

FUTURE OUTLOOK

Antibiotics are considered as a powerful and effective drugs in fighting against infectious diseases caused by bacteria and have been frequently used for decades worldwide for effective treatment of a variety of bacterial infections. Drug utilization evaluation provides insight into the efficiency of drug use, i.e. whether a certain drug therapy provides value for money and the results of such research are used to help to set priorities for the rational allocation of health care budgets.

The implementation of proper screening programmes would actually help in overcoming and reducing the risk of adverse drug reaction as well as antibiotic resistance among patients. Clinical pharmacists and other medical professionals need to play vital role in minimizing the antibiotic problems by conducting continual awareness programs regarding up-to-date prescribing guidelines in the hospital and also minimizing the antibiotic resistance. The active participation of clinical Pharmacists in the clinical ward rounds and documentation of Pharmacist observation on prescription in patient folder is highly recommended for safety and drug monitoring.

The awareness of the prevalence of various pathogens and resistance patterns in the hospitals and exercising good judgment in selection of the antibiotic regimen by the physicians would help a lot in overcoming the problem regarding the irrational use of antibiotics. The rational use of antibiotics can be improved by restricting the use of antibiotics based on guidelines laid by concerned health organisations and those guidelines should be regularly reviewed and regular updated whenever necessary. The study seeks to monitor, evaluate and suggest modifications in prescribing habits so as to make medical care rational and cost effective.

CONTENTS

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Sri Ramakrishna Hospital

Medical Service : M/s. S.N.R. SONS CHARITABLE TRUST

SRI RAMAKRISHNA HOSPITAL ETHICAL COMMITTEE

395, SAROJINI NAIDU ROAD, SIDHAPUDUR, COIMBATORE - 641 044.
Phone : 0422 - 4500000, 4500201, Grams :"RAMHOSP" Fax : 0422-2240521
E-mail : dean@snrsonstrust.org, website : sriramakrishnahospital.com
Ethics Committee Registration No. ECR/690/Inst/TN/2014

SRH/EC.5-9/2016-17 26th February 2016

ETHICAL CLEARANCE CERTIFICATE

Project title: "Drug Utilization Evaluation of Antibiotics at a Tertiary Care Hospital".

Researcher: **Mr.Sanoj Panikar**
M.Pharmacy II year,
Department of pharmacy Practice,
College of Pharmacy,
Sri Ramakrishna Institute of Paramedical Sciences,
Coimbatore – 641 044

The following members of the ethics committee were present at the meeting held on 20.02.2016 at 3.00pm at New Auditorium, Sri Ramakrishna Hospital Campus, Coimbatore.

SI NO	Members Name	Qualification	Designation	Address	Affiliation To the Institution Yes/NO
1.	Dr.P.Murali	M.Sc.,Ph.D., D.Sc	Scientist Mg. Director & CEO	Mg.Director & CEO Evolve Biotech Pvt.Ltd., 401 – 405, 4th floor Ticel Bio park Ltd, Taramani, Chennai - 13	No
2.	Dr.P.Sukumaran	MS., M.Ch., FIACS	Scientific / EC Member Secretary Dean	Dean Sri Ramakrishna Hospital, 395, Sarojini Naidu Road, Sidhapudur, Coimbatore	Yes
3.	Dr.T.Mohan Kumar	MD.,D.Sc., AB.,DPPR., FCCP.,	Clinician	Sr.Consultant Pulmonologist Sri Ramakrishna Hospital, 395, Sarojini naidu Road, Sidhapudur, Coimbatore.	Yes
4.	Dr.S.Rajagopal	M.Ch.,	Clinician	Sr. Consultant Neuro Surgeon Sri Ramakrishna Hospital, 395, Sarojini naidu Road, Sidhapudur, Coimbatore.	Yes

Sri Ramakrishna Hospital

Medical Service : M/s. S.N.R. SONS CHARITABLE TRUST

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E-mail : dean@snrsonstrust.org, website : sriramakrishnahospital.com
Ethics Committee Registration No. ECR/690/Inst/TN/2014

5.	Dr.R.Lalitha	DGO.,(OG)	Clinician	Sr.Consultant Gynecologist & HOD Sri Ramakrishna Hospital, 395, Sarojini naidu Road, Sidhapudur, Coimbatore.	Yes
6.	Dr.T.K.Ravi	M.Pharm Ph.D	Scientific Member	Principal Sri Ramakrishna College of pharmacy 395, Sarojini naidu Road, Sidhapudur, Coimbatore.	Yes
7.	Dr.N.Paramasivan	MBBS.,MD	Basic Medical Scientist	Prof.of pharmacology and HOD Sri Ramakrishna Dental College and Hospital, Coimbatore.	Yes
8.	Dr.M.Rangasamy	B.E., M.Sc., Ph.D.,	Lay Person	Former Professor Government College of Technology, Coimbatore.	No

This is to certify that the research work entitled "Drug Utilization Evaluation of Antibiotics at a Tertiary Care Hospital", placed before the Institutional Ethical Committee has been approved as there is no objection to do this research work.

This ethics committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report.

The Ethics Committee wishes his well in his research.

Yours Truly,

Member Secretary,

Institutional Human Ethics Committee,

Dr. P. SUKUMARAN, M.S.,M.Ch.,FIACS.,
Dean
SRI RAMAKRISHNA HOSPITAL,
395, Sarojini Naidu Road,
Sidhapudur, Coimbatore-641 044.

COLLEGE OF PHARMACY

Sri Ramakrishna Institute of Paramedical Sciences,
Coimbatore
Ph.: 0422- 4500297
Email: pharmacy_practice@rediffmail.com

PATIENT CONSENT FORM

Project Title: "DRUG UTILIZATION EVALUATION OF ANTIBIOTICS AT A TERTIARY CARE HOSPITAL"

I, MURUGESAN have been made understood the necessity of the work entitled **"Drug Utilization Evaluation of Antibiotics at a Tertiary Care Hospital" that is being carried out by Sanoj Panicker, II year** M. Pharm, (Pharmacy Practice) in College of Pharmacy, SRIPMS, Coimbatore. I voluntarily hereby agree by giving my consent to participate in this study and provide the necessary co-operation for the same.

Place: Coimbatore

Date:

Signature of the Patient/By-stander:

Name of the Patient: MURUGESAN

Name of the By-stander: Lekha

Chitra

Signature of the Supervisor:

Mrs. B. Chitra, M. Pharm, (Ph.D).,
Assistant Professor and Head ,
Pharmacy Practice,
College of Pharmacy, SRIPMS,
Coimbatore-44

Signature of the Investigators:

Mr. Sanoj Panicker,
II M. Pharm, Pharmacy Practice,
College of Pharmacy, SRIPMS,
Coimbatore-44

COLLEGE OF PHARMACY

Sri Ramakrishna Institute of Paramedical Sciences,
Coimbatore-44
Ph: 0422- 4500297, Email: pharmacy_practice@rediffmail .com

PATIENT INFORMATION FORM

Project Title: Assessment and prevention of risk for development of cardiovascular diseases in geriatric population with chronic kidney disease

I, **Sanoj Panicker,** II year M.Pharm., (Pharmacy Practice)student of College of Pharmacy, SRIPMS, Coimbatore which is attached to Sri Ramakrishna Hospital Coimbatore, pursuing a dissertation work, entitled"**Drug utilization evaluation of antibiotics at a tertiary care hospital"**which has to be submitted to the Tamil Nadu Dr.M.G.R.MedicalUniversity, Chennai for partial fulfillment for the award of degree of Master of Pharmacy.The details about the patient and the treatment are required by the investigator for carrying out the dissertation. It is here by assured that the details collected are only for the purpose of research and it will helpful to the patient and care giver. It is also assured that the information obtained from the patient will be maintained confidentially. We hope you will provide us the necessary co-operation for the above mentioned work by providing a written consent.

Thanking you

Chitra

Signature of the Supervisor

Mrs. B. Chitra, M.Pharm, (Ph.D).
Assistant Professor
Department of Pharmacy practice,
College of Pharmacy, SRIPMS,
Coimbatore-44

Panicker

Signature of the Investigator

Mr. Sanoj Panicker,
II M.Pharm
Department of Pharmacy Practice,
College of Pharmacy, SRIPMS,
Coimbatore-44

DEPARTMENT OF PHARMACY PRACTICE
College of Pharmacy, SRIPMS, Coimbatore - 44.
Email: pharmacy_practice@rediffmail.com Phone: 0422-4500297

Case No.: 41

DRUG UTILIZATION EVALUATION OF ANTIBIOTICS AT A TERITIARY CARE HOSPITAL

DATA ENTRY FORM

PATIENT DETAILS

Name	Age	Sex	Wt.	Ht.	BMI	IP No.	Dept.	DOA	DOD
Mr. Murugesan	71Y	M	52kg	173cm	17.37kg/m²	201641088S		16-4-16	28-4-16

REASONS FOR ADMISSION complaints of acute urinary retention, bladder catheterized outside, H/O constipation

PAST MEDICAL HISTORY
K/C/O DM/CAD, Post CABG

PAST MEDICATION HISTORY

SOCIAL HISTORY — **Known Allergies :** Nil

Smoker : Y/N ✓ — **Alcoholic : Y/N** ✓
Tobacco in any form : Y/N ✓ — **None :**

Marital Status : Married

Vital Signs											Blood sugar (mg %)										
Date	D_1	D_2	D_3	D_4	D_5	D_6	D_7	D_8	D_9	D_{10}	**Day**										
Temp.	N	N	N	N	N	N	N	N	N	N	**F.B.S (60-90)**	123									
BP	120/70	140/80	140/90	130/80	130/90	120/80	120/80	130/80	130/80	130/80	**P.P.S (80-150)**										
Pulse	82	80	80	82	80	82	80	80	88	80	**R.B.S (90-110)**										

BLOOD COUNTS

Haemoglobin (g/dl) (11-17g/dl)	TLC (cells/cumm) (5000-10000)	ESR (mm/hr) (M<10; F<20)	Differential Leukocyte Count (%)			
11-3			Polymorphs (10-75%)			
			Lymphocytes(20-50%)			
Platelets (1-4 lakhs)	Clotting Time(1-10min)	Bleeding Time(2-5min)	Basophils (0-1%)			
	3 mins 30 sec	2	Eosinophils (1-6%)			
			Monocytes (8-10%)			

LIVER FUNCTION TESTS								RENAL FUNCTION TESTS			
Total bilirubin				Alk. Phosphatase				Urea (mg %) (20-40)	36		
								Uric acid (mg %) F-2-5, M-2-7			
P.T Time (14 sec)	14			SGPT (5-37 U/L)				Sr. Creatinine (mg %) (0.6-1.4)	1.50		
								eGFR- 46 ml/min			

ELECTROLYTES (mEq/l)					URINE EXAMINATION			
Sodium (130-150)					Colour		Sugar	
Potassium (3.5 – 5.8)					Bile salts		WBC	
Chloride (98-100)					Bile pigment		RBC	
Bicarbonate (22-36)					Albumin		Casts	
					Pus cells		Epithelial cells	

DRUG UTILIZATION EVALUATION OF ANTIBIOTICS AT A TERITIARY CARE HOSPITAL

Sl.No	Antibiotics prescribed		Dose	Dosage Form	Freq	Class
	Brand Name	Generic Name				
1	Inj. Tazar	Piperacillin + Tazobactum	4.5g	Injection	BD	Penicillin
2.	Inj. metrogyl	metronidazole	100ml	Injection	BD	Nitroimidazole
3.	Inj Zanocin	Ofloxacin	200mg	Injection	OD	Quinolones

Sl.No	Antibiotics Prescribed	Cost	Alternative Drug	Cost
1.	Inj Tazar	220	Taromac	207.5
2.	Inj. metrogyl	15.3		
3	Inj. Zanocin	86.68	Zanflox	84.00

General Examination

Patient conscious, GC fair, Afebrile, No Pedema
No Lymphadenopathy

CVS: S_1S_2 (+)

RS: B/L AE (+)

P/A: soft

DRE: Grade 1 firm prostate

DEPARTMENT OF PHARMACY PRACTICE
College of Pharmacy, SRIPMS, Coimbatore - 44.
Email: pharmacy_practice@rediffmail.com Phone: 0422-4500297

Case No.:

Culture Sensitivity: Pus culture (Discharge)	**No. of organisms isolated:** 1
Sample:	**Organism isolated:** Klebsiella pneumonia
Sensitive to: Amikacin, Imipenem, Meropenem	
Resistant to: Ampicillin, Cotrimoxazole, Gentamicin, Ceftriaxone, Cefoperazone, Ceftazidime, Piperacillin / Tazobactam, Doxycycline	

Other Investigations:
Activated partial Thromboplastin Time

Diagnosis: Prostatic Abscess, Diabetes mellitus, CAD - S/P CABG

Drugs Prescribed

S. No.	Drugs		Strength	Route of admin.	Days of Treatment										
	T. Name	G. Name			D_1	D_2	D_3	D_4	D_5	D_6	D_7	D_8	D_9	D_{10}	D_{11}
01	IVF		10	IV	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
02	Inj. Tazar	Piperacillin	4.5g BD	IV	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
03	Inj. Zanocin	Ofloxacin	200mg Pooma	IV	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
04	T. Pantodose	Pantoprazole	40 mg	Oral	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
05	T. Silofast D	Silodosin	8mg	Oral	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
06	T. Dolo	Paracetamol	650 mg	Oral	✗	✗	✗	✗	✓	SOS	SOS	✓	✓	SOS	✓
07	T. Voglidose	Voglidose	0.3 mg	Oral	✗	✗	✗	✗	✗	✗	✗	✗	✗	✓	✗
08	Inj. Metrogyl	Metronidazole	100ml	IV	✗	✗	✗	✗	✗	✗	✗	✗	✓	✓	✓
09	Inj Actrapid	Insulin	4-4-0	SC	✗	✗	✗	✗	✗	✗	✗	✓	✓	✓	✗
10	Inj Insulated	Insulin	0-0-4	SC	✗	✗	✗	✗	✗	✗	✗	✓	✓	✗	✗
	Inj Mixtard	Human insulin	8-0-4	SC											

DEPARTMENT OF PHARMACY PRACTICE
College of Pharmacy, SRIPMS, Coimbatore - 44.
Email: pharmacy_practice@rediffmail.com Phone: 0422-4500297

Case No.:

DRUG INTERACTIONS/ADVERSE DRUG REACTIONS

DRUGS	EFFECT	INFERENCE	INTERVENTION
Tarai + Sibofast	moderate	Regular monitoring required	
metrogyl + Voglibose	Minor	Dose adjustment Required	

ANYOTHER INTERVENTIONS MADE

DISCHARGE MEDICATION:

S. No.	Drugs		Strength	Route of admin.	Days of Treatment
	T. Name	G. Name			
01	T. Zanoxy (AP)	Ofloxacin	200mg	Oral	
02	T. Ciplin DSR (DT)	Ciprofloxacin	200mg	Oral	
03	T. Pantodac DSR	Pantoprazole	40mg	Oral	
04	T. Sibofast D	Sibodosin	8mg	Oral	
05	C. Zinconit	Nikemin		Oral	
06	Inj. Mixtard	Zinc Cop	16-0-16	~~Oral~~ SC	
07	T. Voglidase	voglibose	0.3mg (with food)		
08	Ecospirin	Aspirin	20mg	Oral	

Signature of the Principal Investigator
NAME: Sanoj Panicker
II nd Year M. Pharm., (Pharmacy Practice)

Signature of the Supervisor
Dr. B. Chitra, M. Pharm., (Ph. D)
Asst. Professor, Pharmacy Practice

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

CDSCO
Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India,
FDA Bhavan, ITO, Kotla Road, New Delhi
www.cdsco.nic.in

(AMC/ NCC Use only
AMC Report No.
Worldwide Unique no.

A. Patient Information

1.Patient Initials	2.Age at time of Event or date of birth	3. Sex ☐M ☑F
IP No. 20160865	56 yrs	4. Weight ____Kgs

12. Relevant tests / laboratory data with dates

B .Suspected Adverse Reaction

5. Date of reaction stated (dd/mm/yyyy) 14/4/16

6. Date of recovery (dd/mm/yyyy) 17/4/16

7. Describe reaction or problem

56 year old lady came with complaints of pain in the ilieal region. She is a/c/o HT and DM for past 20 years. She was prescribed with Inj Taxar 4.5gm for preventing hospital acquired infections and she experienced constipation

13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

14. Seriousness of the reaction

- ☐ Death (dd/mm/yyy)____
- ☐ Life threatening
- ☐ Hospitalization-initial or prolonged
- ☐ Disability
- ☐ Congenitial anomaly
- ☐ Required intervention to prevent permanent impairment / damage
- ☐ Other (specify)

15. Outcomes

- ☐ Fatal
- ☐ Continuing
- ☐ Recovering
- ☑ Recovered
- ☐ Unknown
- ☐ Other (specify)____

C.Suspected medication(s)

S.No	8. Name (brand and /or generic name)	Manufacturer (if known)	Batch No./ Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known give duration)		Reason for use of prescribed for
								Date started	Date stopped	
i.	Inj. Taxar	Lupin		10/2017	4.5gm	IV	BD	11/4/16	19/4/16	for preventing Nosocomial
ii.										infections
iii.										
iv.										

Sl.No As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced dose
i.			✓					✓		
ii.										
iii.										
iv.										

11. Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)

1) T. Diovan 80mg 5) T. Nebicip/30mg
2) T. Betaken 50mg 6) T. Alphadol 0.25g
3) T. Torsvast 10mg 7) Inj. Ranitidine 40mg
4) T. Pramadol

D. Reporter (see confidentiality section in first page)

16. Name and Professional Address : Sanoj Panicker

Pin code : — E-mail —

Tel. No. (with STD code): —

Occupation — Signature Panicker

17. Causality Assessment: Possible

18. Date of this report (dd/mm/yyyy): 19-4-16

Naranjo Adverse Drug Reaction Probability Scale

Question	Yes	No	Do Not Know	Score
1. Are there previous *conclusive* reports on this reaction?	+1	0	0	+1
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	0
3. Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	+1	0	0	+1
4. Did the adverse event reappear when the drug was re-administered?	+2	-1	0	0
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	0
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	0
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	0
9. Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	+1	0	0	0
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	+1
			TOTAL SCORE:	3

Modified from: Naranjo CA et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981; 30: 239-245.